EXHIBIT 4

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Cuyahoga, et al. v. Purdue Pharma L.P., et al.,* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

CUYAHOGA COUNTY'S
REPLACEMENT SUPPLEMENTAL RESPONSE AND OBJECTIONS TO
MANUFACTURER DEFENDANTS' INTERROGATORIES

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and the Case Management Order in *In re National Prescription Opiate Litigation*, No. 1:17-cv-2804 (Dkt. No. 232), Cuyahoga County ("Plaintiff") hereby provide its supplemental response and objections to Manufacturer Defendants' Interrogatories, as follows:

OBJECTIONS

The following objections apply to each Interrogatory. To the extent that certain specific objections are cited in response to an individual Interrogatory, those specific objections are provided because they are applicable to that specific Interrogatory and are not a waiver of the other objections applicable to information falling within the scope of such Interrogatory.

1. Plaintiff objects to each Interrogatory to the extent they are overly broad, vague, unduly burdensome, seek information that is not relevant to any party's claim or defense, or seek to impose obligations or require actions beyond those required by the Rules of Civil Procedure, the ESI Protocol entered in this matter or the Local Rules of the United States District Court of the Northern District of Ohio.

Third, with its branded products, Mallinckrodt also used unbranded "PocketGuides" that contained the following misrepresentations:

"Risk of addiction is low" (under acute pain heading)

"Single-entity opioids have no maximum dose but may be limited by side effects"

"Pseudoaddiction" = "Drug-seeking behavior focused on pain relief, due to undertreatment of pain."

See, e.g., MNK-T1_0001786865, MNK-T1_0002248919.

In addition, Mallinckrodt participated in conferences and tradeshows in which it engaged in the marketing of generic controlled substances manufactured by Mallinckrodt. See, e.g., Deposition Testimony and Exhibits of Steven Becker, Jane Williams and Bonnie New.

PPLP004149692
PPLP004163244
PPLP004134382
PPLP003277170
PPLP003277170

Plaintiff also incorporates its answers and objections to Manufacturer Interrogatory No. 9 and Distributor Interrogatory No. 27. Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 9:

Identify and describe all statements or omissions made or disseminated in the Plaintiff's county, city, village, or township by any Defendant (or any other person whose statements you attribute, in whole or in part, to a Defendant) that you claim were false, misleading, unfair, deceptive or otherwise actionable. Include in your identification of each statement or omission: (i) the name, employer, and position(s) of the speaker, writer, or other person who issued the

statement; (ii) the name(s) and position(s) of the recipient(s) of such statement; (iii) when and where the allegedly false, misleading, or deceptive statement was made; (iv) a description of the content of the statement; and (v) all reasons you claim the statement was false, misleading, or deceptive.

Response to Interrogatory No. 9:

Plaintiff repeats and reasserts their prior objections and adopt their prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe "all" statements or omissions made or disseminated in Plaintiff's jurisdiction by any Defendant that were false, misleading, unfair, deceptive or otherwise actionable. Further objecting, the Interrogatory contains a reference to an undefined phrase, "otherwise actionable." Plaintiff further objects to the extent it seeks information that is uniquely in Defendants' possession or publicly available, and with a specificity that imposes an undue burden on Plaintiff. Hundreds of depositions of fact witnesses have been taken of Defendants and the bellwether fact witnesses, utilizing hundreds of exhibits. Millions of documents have been exchanged. The discovery performed to date, including depositions, written responses and document productions, provides details of statements and omissions made or disseminated that were false, misleading, unfair and deceptive. It is not practicable to specifically identify each and every statement and omission herein. Plaintiffs reserve the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic. Also, Plaintiffs' discovery, document review and investigation are continuing, and they reserve their right to rely upon and introduce further evidence addressing this topic.

Notwithstanding and without waiving all objections, Plaintiff responds the following false, misleading, unfair and deceptive statements include:

I. Defendants' drugs were different; less addictive or abusable than opioids of the past

   a. Extended release drugs and/or q12 dosing- had fewer peaks and valleys and less chance of addiction and abuse

b. Abuse deterrent formulations deter abuse

c. Abuse deterrent formulations are safer than non-abuse deterrent formulations

II. Concerns about Addictive Nature of Opioids Had been Overblown

a. Science was now showing they were not as addictive as once thought

b. True patients in pain cannot get addicted – pain protects against addiction

c. Signs of addiction as simply symptoms of undertreated pain or "pseudoaddiction"

d. Problems only occur when opioids are abused or used illegally- addicts are bad people who knowingly abused the drugs, not good people who were seeking treatment for legitimate ailments.

e. If taken as prescribed risk is almost nonexistent:

i. addiction less than 1% or low or rare
ii. patients can be easily tapered off opioids
iii. dependence is not a significant concern - only physical and easily reversed

f. Drug abusers and potential addicts can be easily identified and therefore not prescribed opioids, or prescribed opioids and monitored closely

g. Even patients at high risk of addiction can be safely prescribed opioids by using risk-mitigation strategies such as pain contracts

III. Pain should be treated with opioids as a first resort.

a. Undertreated pain should be treated with opioids

b. There is more risk of leaving pain untreated than using opioids to treat pain.

c. Opioids offer more effective pain control and are safer than alternatives.

d. Defendants' opioids will make your life better without risk

e. No maximum dose- if you are in pain more opioids could be given without additional risk (i.e., "titrate to effect" concept from cancer/palliative care should be used with chronic pain)

f. Opioids can be prescribed for any pain condition without risk

g. Opioids can be prescribed for any duration without risk

h. Opioids can be prescribed to any age group without risk

i. "Round the clock" dosing should be used for chronic pain rather than "as needed" dosing

j. "Breakthrough pain" applies to chronic pain, not just cancer pain, and short-acting opioids should be used to supplement long-acting opioids for that reason.

Falsehood	Explanation
The risk of addiction from chronic opioid therapy is low	When it launched OxyContin, Purdue cited in promotional and educational materials a single paragraph from a letter published

Falsehood	Explanation
	in 1980 by Dr. Hershel Jick and Jane Porter in the New England Journal of Medicine as evidence of the low risk of addiction to opioids. In fact, Purdue included reference to this letter in a 1998 promotional video entitled, "I got my life back," in which Dr. Alan Spanos states, "In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%." Until April 2012, Endo stated on its website that "…patients treated with prolonged opioid medicines usually do not become addicted;" a statement echoed on the website of its close affiliate, APF. Endo also published and distributed multiple pamphlets and brochures downplaying addiction as it related to opioids. For example, "Living with Someone with Chronic Pain", stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem.[3] Other publications, include but not limited to "Pain: Opioid Facts," "Understanding Your Pain: Taking Oral Opioid Analgesics" and "Pain: Opioid Therapy." Janssen claimed on its unbranded website – www.PrescribeResponsibility.com – that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients." Janssen also published a patient education guide entitled "Finding Relief: Pain Management for Older Adults" describing opioid addiction as a myth and that "many studies show opioids are *rarely* addictive…" which, until recently, was available online. Cephalon sponsored a 2007 publication from APF entitled "Treatment Options: A Guide for People Living with Pain" which taught that opioid addiction is rare. Actavis published material that claimed it is "less likely" to become addicted to opioids in those who "have never had an addiction problem." The same publication notes that a need for a "dose adjustment" is the result of tolerance, and "not addiction." A 2007 guide for prescribers published under Actavis's copyright states that Kadian is more difficult to abuse and less addictive than other opioids.[4] Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance in 2010 which

[3] ENDO-CHI_LIT-00195455.

[4] ACTAVIS0006823.

Falsehood	Explanation
	promoted a book entitled "Defeat Chronic Pain Now!" in which opioids were stated to "rarely" cause addiction.
To the extent there is a risk of addiction, it can be easily identified and managed	Purdue and Cephalon sponsored the APF's publication, "Treatment Options: A Guide for People Living with Pain" in 2007, which falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed." Janssen stated on its website – www.PrescribeResponsibly.com – that opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors. Purdue also sponsored a 2011 webinar taught by Dr. Lynn Webster entitled "Managing Patient's Opioid Use: Balancing the Need and Risk" wherein prescribers were told that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." Endo paid for a 2007 supplement for continuing education credit in the "Journal of Family Practice" entitled "Pain Management Dilemmas in Primary Care: Use of Opioids" which recommended screening patients and the use of the Opioid Risk Tool.
Signs of addictive behavior are "psuedoaddiction," requiring more opioids	Cephalon, Endo and Purdue sponsored the Federation of State Medical Board's ("FSMB") publication entitled "Responsible Opioid Prescribing" in 2007 which stated that such behaviors as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids and hoarding are all signs of "pseudoaddiction" (not genuine addiction). Purdue published an unbranded pamphlet entitled "Clinical Issues in Opioid Prescribing" in 2005 which was circulated through 2007 and available on its website through 2013. This pamphlet stated that "illicit drug use and deception" were not evidence of true addiction, but rather "pseudoaddiction." Endo sponsored a CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which promoted pseudoaddiction. Janssen sponsored, funded and edited a website entitled "Let's Talk Pain" which in 2009 stated that pseudoaddiction "…refers to patient behaviors that may occur when pain is undertreated…"
Opioid withdrawal can be avoided by tapering	Endo sponsored an educational program entitled "Persistent Pain in the Older Adult" which claimed that withdrawal symptoms could be avoided by simply tapering a patient's opioid dose over ten days. Similarly, Purdue sponsored APF's publication "A Policymaker's Guide to Understanding Pain & Its Management" which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation." Neither Defendant explained the significant hardships associated with cessation of use.

Falsehood	Explanation
Opioid doses can be increased without limit or greater risks	Purdue omitted the increased risk of respiratory distress and death from increasing opioid dosage from its 2010 "Risk Evaluation and Mitigation Strategy" for OxyContin. Endo published on its website a patient education pamphlet entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" that responds to the question, "If I take the opioid now, will it work later when I really need it?" with "The dose can be increased…You won't 'run out' of pain relief." Purdue and Cephalon also sponsored APF's 2007 "Treatment Options: A Guide for People Living with Pain" which taught patients that opioids have "no ceiling dose" and are therefore safer than NSAIDs.
Long-term opioid use improves functioning	Janssen promoted Duragesic through an ad campaign as improving a patient's functioning and work productivity. Janssen's "Let's Talk Pain" website featured a video interview claiming that opioids were what allowed a patient to "continue to function." Similarly, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association stating, "There Can Be Life With Relief" and implying that OxyContin would help users' function; however the FDA noted that Purdue failed to warn that patients could die from taking OxyContin. Purdue also ran advertisements in medical journals in 2012 touting that OxyContin would help a "writer with osteoarthritis of the hands" work more effectively. Since May 2011, Endo has distributed and made available on its website – www.Opana.com – a pamphlet implying that patients with physically demanding jobs would achieve long-term pain relief and functional improvement. Mallinckrodt's website claims that "[t]he effective pain management offered by our [opioids] helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."
Alternative forms of pain relief pose greater risks than opioids	Purdue and Cephalon sponsored APF's publication entitled "Treatment Options: A Guide for People Living with Pain" warning of increased risks if NSAIDs are "taken for more than a period of months;" falsely attributing 10,000 to 20,000 deaths annually to NSAID overdoses when the figure is closer to 3,200. In 2009, Janssen sponsored a publication entitled, "Finding Relief: Pain Management for Older Adults" which listed dose limitations as "disadvantages" of other pain medicines. It also listed a number of serious health effects as disadvantages of NSAIDs while only listing "upset stomach or sleepiness" and constipation as disadvantages of opioids. Purdue and Endo sponsored a CME issued by the AMA in 2003, 2007, 2010 and 2013 entitled "Overview of Management Options" which taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

Falsehood	Explanation
OxyContin provides twelve hours of pain relief	In 2000, Purdue advertised that OxyContin provides "Consistent Plasma Levels Over 12 Hours;" however the oxycodone does not enter the body at a linear rate, releasing a greater proportion upon administration and gradually tapering over 12 hours. These 12-hour dosing advertisements ran in the *Journal of Pain* in February 2005 and the *Clinical Journal of Pain* in 2006.
New formulations of certain opioids successfully deter abuse	Purdue presented an article in 2013 based on a review of data from poison control centers concluding that its ADF OxyContin can reduce abuse, but failed to acknowledge that abuse merely shifted to other drugs and that there were actually more harmful exposures to opioids after the reformulation. In 2016, Dr. J. David Haddox, VP of Health Policy for Purdue, falsely claimed that the evidence does not show Purdue's ADF opioids are being abused in large numbers. Endo's promotion of its Opana ER also tended to omit material facts according to a May 2012 letter from the FDA to Endo. Endo submitted a citizen petition asking the FDA for permission to label Opana ER as abuse-resistant, and also went so far as to sue the FDA to force expedited consideration of this change. Endo falsely promoted Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that it was actually crush-resistant and less likely to be abused (as stated in a June 14. 2012 press release). Endo initiated journal advertisements that appears in April 2013 stating Opana ER was "designed to be crush resistant." Likewise, Actavis copyrighted a guide for prescribers representing that Kadian is more difficult to abuse and less addictive than other opioids.[5] Mallinckrodt promoted both Exalgo and Xartemis XR as specifically formulated to reduce abuse, going so far as to state, "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."
Endo: "[M]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Taking a Long-Acting Opioid: What Does It Mean to Me* (2008); Caregiver Booklet (2009).	This is demonstrably false and misleading.

[5] ACTAVIS0690598.

Subject to and without waiving all objects, Plaintiff identifies the following recipients of false, misleading or deceptive statements from Defendants within Plaintiff's region: Dr. Michael M. Hughes (President, Summa Health System), Dr. Kendrick Bashor (Physician, University Primary Care Practices, Inc.), Dr. Michael Louwers (Physician, Physical Medicine Rehabilitation), Dr. William Lonsdorf (Physician, Suburban South Family Physicians), Dr. Syed Ali (Anesthesiology/Pain Medicine), Dr. William Reed (Physician, Summa Health Medical Group), Dr. Gregory Hall, Dr. Tony Lababidi, and Dr. Clayton Seiple (Physician, Osteopathic Manipulative Therapy Specialist, United Health Network). Furthermore, Plaintiff directs Manufacturing Defendants to their call notes and other records of sales activity, which chronicle statements or omissions made within Cuyahoga County.

Plaintiff also refers Defendants to ¶¶ 47 – 147 of the Second Amended Complaint.

For purposes of illustration, including by way of examples, Plaintiff supplement their responses as follows:

> Through a massive marketing campaign premised on false and incomplete information, Cephalon and/or Teva engineered a dramatic shift in how and when opioids are prescribed. Cephalon and/or Teva asserted that the risk of addition was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of long-term opioid use. Cephalon and/or Teva's goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer in opioid-tolerant patients, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.
>
> Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Cephalon and/or Teva dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result.

Cephalon and/or Teva employed the same marketing plans and strategies and deployed the same messages in and around Ohio, including in Plaintiff's community, as they did nationwide. The deceptive marketing schemes included, among others, (a) false or misleading direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known as "detailing;" (c) false or misleading materials, speaker programs, webinars, and brochures; and (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by Cephalon and/or Teva, as discussed in response to Interrogatory No. 8. In addition to using third parties to disguise the source of their misinformation campaign, Cephalon and/or Teva also retained the services of certain physicians, known as "key opinion leaders" or "KOLs" to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

Cephalon and/or Teva have made false and misleading claims, contrary to the language on their drugs' labels regarding the risks of using their drugs that: (a) downplayed the serious risk of addiction; (b) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d) claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher dosages; and (f) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Cephalon and/or Teva have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support their claims.

Cephalon and/or Teva have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Cephalon and/or

Teva Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups. And even though the Cephalon and/or Teva knew doctors, healthcare professionals and the medical community did not have a medical understanding of opioids and risks of opioid abuse, they did not disseminate messages consistent with their product labels that were designed and intended to instruct doctors on the proper use of their opioid products and underscore the abuse and addiction risks associated with those products in order that they would change their prescribing habits so their products would be safely used.

Cephalon and/or Teva Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept their misrepresentations. By way of example, in February 2001, when Cephalon acquired U.S. marketing rights for Actiq, it "repositioned" and "relaunched" Actiq. Prior to the relaunch, "the marketing directive had been to target oncologists, hematologists and pain specialists, with the emphasis being placed on oncology." TEVA_MDL_A_00454816 at 824 (Cephalon 2002 Marketing Plan). Cephalon's strategy was to shift the target market from oncologists to other physicians. *See id.* at 829. Cephalon's 2002 marketing plan stated, "[w]hile oncologists obviously use Actiq to treat BTCP," anesthesiologist and pain specialists "may feel comfortable with Actiq's potential in other pain states regardless of the narrow BTCP indication." *Id.* at 827. Cephalon cited Actiq's use for, among other things, lower back pain, adhesions, headache, osteoarthritis, fibromyalgia, rheumatoid arthritis and lupus. *Id.* The 2003 Actiq Marketing Plan targeted anesthesiologists and the PowerPoint presentation by Randy Spokane from the same year highlighted anesthesia, pain management, physical medicine and pain, rheumatologists, neurologists and primary care physicians. See TEVA_CHI_00042882 at 895; TEVA_MDL_A_09062111 at slide 14. Cephalon and/or Teva targeted physicians lacking experience in the use of Schedule II opioids and the treatment of cancer

patients, and to patients without malignant cancer and without opioid tolerance. In addition to targeting more physicians, Cephalon's campaign also focused on breakthrough pain ("BTP") instead of breakthrough cancer pain ("BTCP"). *See* 2002 National Sales Meeting Power Point ("Cephalon is successfully repositioning Actiq as a viable and uniquely effective BTP treatment option".)

Cephalon and/or Teva promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff in their offices – and small group speaker programs. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including doctors in Ohio. For example, on information and belief, the Cephalon and/or Teva's detailers falsely and misleading state the following:

a. Described the risk of addiction as low or failed to disclose the risk of addiction. For example, the training modules used to educate Cephalon and Teva's sales force taught that in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon. See TEVA_MDL_A_00890304 at 354. The training modules also stated that pain appears to reduce the euphoric effects of opioids, so people taking opioids to manage their pain may be at lower risk for addiction. See TEVA_MDL_A_00890304 at 358.

b. Describe their opioid products as "steady state" – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Discuss "pseudoaddiction". For example, the training modules used to educate Cephalon and/or Teva's sales force indicated patients in pain do not usually become addicted to opioids. The modules taught the sales force that if patients receive inadequate pain relief, they may exhibit drug-seeking behaviors, i.e. pseudoaddiction. See TEVA_MDL_A_00890304 at 358; Day Depo. 160:23 to 161:8. Other Cephalon and/or Teva employees also misled Ohio sales representatives and physicians on the topic of pseudoaddiction. Randy Spokane taught that pseudoaddiction means patients aren't psychologically or physically

addicted, they are just in fear of running out of medication. Spokane Depo. 102:5-23; Morreale Depo. 73:3 to 76:8;

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

Because these detailers must adhere to scripts and talking points drafted by the Teva, it can be reasonably inferred that most, if not all, of Cephalon and/or Teva's detailers made and continue to make these misrepresentations to the thousands of doctors they have visited and continue to visit. Cephalon and/or Teva have not corrected this misinformation.

By way of example, Cephalon's 2003 Marketing Plan states, "most pain experts believe that pain is pain regardless of the source of the pain or disease state. Therefore, messaging for both targeted segments, pain specialists and oncologists, will be identical and will include the key marketing messages…" TEVA_CHI_00042882 at 933. The marketing plans were shared with the sales representatives, who utilized this information during direct sales calls to Ohio physicians. *See* Sippial Dep. Tr. 91:13-93:16. The marketing message "pain is pain" was utilized with the sales force. Kaisen Dep. Tr. 25:9-17. Cephalon also distributed coupons for free Actiq samples or coupons to doctors, some of whom passed them on to non-cancer patients.

For example, the documents produced in this litigation show that Cephalon and/or Teva identified "opiophobia" as a potential roadblock to the sale of Actiq and Fentora. *See* TEVA_MDL_A_09061553 at slide 21; TEVA_MDL_A_09062111 at slide 17; TEVA_CHI_00043010 at 012 and 016. The marketing team and sales force for Cephalon and/or Teva fought the physicians' fear of opioids (i.e. opiophobia) by training sales representatives to discuss opioids with physicians and to reassure them of their safety. The sales force was trained to

tell physicians that Cephalon and/or Teva's opioid products had "less potential for abuse" and a "cleaner profile." See TEVA_MDL_A_09062111 at slides 11 and 12. Cephalon and/or Teva's marketing and sales teams were taught, and passed along the message to prescribers, that "undertreatment of pain is a widespread problem because of opiophobia." See TEVA_CHI_00043010 at 016. For example, Cephalon and/or Teva sales representative, Valerie Kaisen, testified that opiophobia was always a concern. See Kaisen Dep. Tr. 144:19-145:4.

The Cephalon and/or Teva sales' force was trained using modules which contained misrepresentations and omissions that were subsequently communicated to physicians. For example, Matthew Day's training of sales representatives included a strategy to "allay [the] fear of opioids." *See* TEVA_MDL_A_08657218. Mr. Day used the term opiophobia with the sales representatives he trained, including those calling on Ohio physicians.

Cephalon and/or Teva also identified doctors to serve, for payment and other remuneration, as Key Opinion Leaders ("KOLs") and on their speakers' bureaus and to attend programs with speakers and meals paid for by the Cephalon and/or Teva. These KOLs and speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script and messaging prepared by Cephalon and/or Teva. These presentations conveyed misleading information, omitted material information including about the proper use and risks of their opioid products or the products used to treat, and failed to correct prior misrepresentations about the risks and benefits of opioids. For example, KOLs like Dr. Steven Simon and Dr. Steven Singer were hired by Cephalon to serve as speakers at National Consultants' Meetings in places like New Orleans. These meetings were also attended by Cephalon employees, including marketing personnel and sales representatives. During these meetings, Dr. Steven Simon spoke on Pain Management Application: Chronic Back Pain/Arthritic Pain. Dr. Steven Singer spoke on Pain Management Application: Migraine Headache. Cephalon and/or Teva paid third

party medical marketing firms and physicians to help promote Actiq and Fentora. *See* 2004 Actiq Marketing Sales Training, July 2004 (crediting Cephalon's success, in part, to "Lots l' MedEd"). The educational programs sponsored by Cephalon focused on expanding awareness of BTP and other forms of non-cancer pain. See TEVA_CHI_00042882 at 937; see also Actiq Consultants Meeting: Event Evaluation.

The Department of Justice also took note of this in its September 29, 2008 Press Release, stating, "[Cephalon] funded continuing medical education programs, through millions of dollars in grants, to promote off-label use of its drugs, in violation of the FDA's requirements," and in its memorandum supporting Cephalon's guilty plea. Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 million & Enter Plea To Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), and Government's Memorandum For Entry of Plea and Sentencing filed on September 29, 2008 in United States of America v. Cephalon, Inc., Crim. No. 08-598 (and attachments thereto).

Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Frequent prescribers are generally more likely to have received a detailing visit, and in some instances, infrequent prescribers of opioids received a detailing visit from Cephalon and/or Teva's detailer and then prescribed Cephalon and/or Teva's opioid products. The sales representatives from Cephalon and/or Teva would use sales reports to vet physicians as "growth targets." *See* Gillenkirk Dep. Tr. 45:2-46:14. These reports included doctors' use of opioids and specialties as factors for potential sales.

Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA prohibited Cephalon

from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm. Despite this, Cephalon conducted a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. See Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 million & Enter Plea To Resolve Allegations of Off-Label Marketing (Sept. 29, 2008). In September 2008, Cephalon agreed o plead gyilty to the charge that it introduced "into interstate commerce . . . drugs that were misbranded through off-label promotion, . . . arising from Cephalon's off-label promotions of its drugs" including Actiq. *See* Sept. 29, 2008 Department of Justice Press Release ("Cephalon promoted Actiq for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. . . [i]t trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label use.").

As part of this campaign, Cephalon used speaker programs and KOLs as referenced above, as well as Continuing Medical Education, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. See "Actiq Publication Project Monthly Status Update," August 2, 2004 (listing publications with topics including a comparison of oral transmucosal fentanyl citrate ("OTFC") and morphine and the use of OTFC for migraine headaches and musculoskeletal pain).

Cephalon and/or Teva also trained, paid and utilized its Speakers, KOLs and sales representatives to present on and/or provide to doctors and other health care providers studies and journal articles generated by Cephalon and/or Teva for off-label uses of Actiq and Fentora, and did not provide sufficient information on the proper use and risks associated with those products. For example, Dr. Arvind Narayana and others authored clinical studies to promote the off-label use and treatment of Fentora by minimizing the risk of off-label use and providing their evidence of the

similarities between cancer BTP and non-cancer BTP. Fentora sales representatives were also permitted to distribute information regarding Fentora's safety and efficacy in neuropathic and back pain to HCPs who inquired about the off – label use of Fentora. *See* Portenoy et. al., *Fentanyl Buccal Tablet (FBT) for Relief of Breakthrough Pain in Opioid - Treated Patients with Chronic Low Back Pain: A Randomized, Placebo – Controlled Study*; Simpson et. al., *Fentanyl Buccal Tablet for Relief of Breakthrough Pain in Opioid - Treated Patients with Chronic Neuropathic Pain: A Multicenter, Randomized, Double Blind, Placebo Controlled Study*.

Another element of Cephalon and/or Teva's marketing plan was to ensure reimbursement and insurance coverage for Actiq and Fentora prescriptions for off-label uses. The companies created a reimbursement assistance program designed to help patients obtain insurance coverage for Actiq and Fentora. In 2005, Cephalon reported that managed care organizations had increased restrictive measures on the reimbursement of Actiq but "managed care has, for the most part, been relatively unsuccessful at slowing or stopping Actiq[.]" See TEVA_CHI_00043010 at 043.

Cephalon and/or Teva capitalized on the off-label marketing of Actiq by focusing on Actiq prescribers in order to market Fentora as a better drug, without adequately informing physicians of the drug's cancer indication and addiction risks. Cephalon implemented a plan to transition doctors from Actiq to Fentora starting in 2006 (when Actiq began to face generic competition and Fentora was approved for the same limited indication as Actiq), even though they knew that most of those doctors were prescribing Actiq for off-label uses and did not fully understand the misuse, abuse and addiction risks associated with those drugs. They did this by convincing them that Fentora was a better and faster-acting medication. Cephalon and/or Teva's Fentora marketing plans from 2005 to 2012 basically follow the same off-label marketing roadmap charted for Actiq, and Cephalon considered its transition from Actiq to Fentora a marketing success.

Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

Cephalon and/or Teva disseminated these deceptive marketing and sales messages on a national basis, including in the State of Ohio. During their depositions, Randy Spokane, Michael Morreale and Matt Day all discussed the training of sales representatives and detailers who called on physicians in Ohio and marketing tactics used in the State of Ohio. *See* Spokane Dep. Tr. 16:18-23; 17:17-18:22; 21:14-20; 43:16-20; Morreale Dep. Tr. 13:14-14:17; 16:22-25; and Day Dep. Tr. 316:6-16; 319:24-320:8; *see also* depositions of Colleen Gillenkirk, Valerie Kaisen and Laura Sippial (Cephalon/Teva sales representatives discussing their detailing activities in Ohio). At annual sales meetings, the sales and marketing plans for Actiq and Fentora were shared. *See* Spokane Dep. Tr. 62:15-23.

In addition, Cephalon and/or Teva in their branded and unbranded marketing efforts omitted key information on the proper use and risks, including the risks of misuse, abuse and addiction, associated with Actiq and Fentora. Cephalon and/or Teva further failed to take the steps

they acknowledged were necessary to ensure safe use of those drugs, as set forth in the Actiq Risk Management Program and the Fentora Riskmap, and the REMS programs for those drugs. *See* TEVA_MDL_A_03272088; TEVA_CHI_00028341; TEVA_MDL_A_08399245; TEVA_MDL_A_01584978; TEVA_MDL_A_07679384; TEVA_MDL_A_07679522. Such steps included using various tools and vehicles, including using their sales force, speakers programs, advertising and publication plans, to convey messaging and to educate doctors about proper patient selection according to their indicated uses, including use only in cancer patients who were opioid tolerant, and about the risks of addiction, misuse and diversion associated with those drugs. *See, e.g.*, TEVA_MDL_A_07424105; TEVA_MDL_A_00267691; TEVA_MDL_A_01583546; TEVA_MDL_A_01583458; TEVA_MDL_A_00038282; TEV_FE00116840. Such steps are parallel and consistent with the steps Plaintiffs claim should have been taken by Cephalon and Teva under Ohio state tort and statutory laws. In fact, as set forth herein, Cephalon and/or Teva instead used these tools and vehicles in their branded and unbranded marketing to convey messaging and educating doctors to the contrary, including that use of Actiq and Fentora was appropriate for off-label chronic use, use in cancer patients and use in opioid-naïve patient populations, and that the risks of misuse, abuse and addiction were minimal and could be managed.

Further, Cephalon and Teva were and remain aware their name-brand and generic opioid products were being prescribed by doctors and other health care providers for conditions other than their indicated use, and without full knowledge and appreciation of the proper use and risks associated with those opioid products. Cephalon and Teva also were and remain aware once a name-brand opioid product lost its patent protection and generic manufacturers such as Teva entered the market for that generic product (including opioid products), the market share for that product was and remains dominated by the generic manufacturers. Cephalon and Teva also were and remain aware generic manufacturers dominate the overall opioid market, including over 90% of the

prescription opioid market as Plaintiffs are informed and believe. Cephalon and Teva also knew at all relevant times that their name-brand and generic opioid products were high-risk Schedule II narcotic prescription products, and as such it was especially important doctors and other healthcare providers be pro-actively educated and informed on the proper use and risks associated with those opioid products, and especially so when they became aware those drugs likely were being improperly prescribed and that patients were becoming addicted. Cephalon and Teva, through their omissions, failed to adequately communicate to doctors and other health care professionals, consistent with their product labels, the proper uses and indications for their name-brand and generic high-risk opioid products, as well as key safety information and risks associated with those opioid products including the risks of misuse, abuse and addiction. Cephalon and Teva's failure to take adequate steps to communicate proper use and risk contributed to the improper use and over-prescription of their name-brand and generic opioid products, leading to unnecessary and widespread addiction of patients and harm to Plaintiffs.

Supplemental information pertaining to Mallinckrodt:

First, Mallinckrodt's 30(b)(6) designee on marketing, Kevin Webb, confirmed that Mallinckrodt utilized a nationwide marketing approach, and that any marketing and advertising materials developed in that approach would have been used in Ohio. See Deposition of Kevin Webb.

Second, Mallinckrodt distributed unbranded pain "pocketcards" in its Generics business that contained the following misrepresentations:

"Addiction rarely occurs unless there is a hx of abuse"

"Most opioid agonists have no analgesic ceiling dose; titrate to relief and assess for adverse effects"

"With older adults, start dose low, go slow, but go!!"

"Use long-acting opioids around the clock for baseline management of persistent pain; Use short-acting opioids PRN (rescue) for breakthrough pain"

"Two drugs of the same class (eg, NSAIDs) should not generally be given concurrently, however long- and short-acting opioids may be prescribed together"

See, e.g., MNK-T1_0002159713, MNK-T1_0002183040, MNK-T1_0001531484.

Third, with its branded products, Mallinckrodt also used unbranded "PocketGuides" that contained the following misrepresentations:

"Risk of addiction is low" (under acute pain heading)

"Single-entity opioids have no maximum dose but may be limited by side effects"

"Pseudoaddiction" = "Drug-seeking behavior focused on pain relief, due to undertreatment of pain."

See, e.g., MNK-T1_0001786865, MNK-T1_0002248919.

In addition, Mallinckrodt participated in conferences and tradeshows in which it engaged in the marketing of generic controlled substances manufactured by Mallinckrodt. See, e.g., Deposition Testimony and Exhibits of Steven Becker, Jane Williams and Bonnie New.

Bates #	Date	Summary
ACTAVIS0584744	3/11/2006	Kadian Market Opportunity presentation prepared for Alpharma Inc. demonstrates that abuse-resistant formula was to fill this market demand ACTAVIS0584779-788 states that prescriber concerns mostly revolve around abuse - ACTAVIS0584795 SimOpt creates market simulations for Kadian's ability to perform under various scenarios against other abuse-deterrent forumlas -ACTAVIS0584807 sees an opportunity in that the "market for abuse-resistant LA opioids is far larger than
ACTAVIS0006823	3/31/2007	2007 Kadian Sales/Marketing brochure "Through its "Learn More about customized pain control with Kadian" material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have

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		never had an addiction problem." Without using the term pseudoaddiction directly, the piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction." (pg. 4).
ACTAVIS0704298	8/29/2007	(See also ACTAVIS0947851, date of documents unclear) "Kadian and Tapering of Opioids" - "In chronic pain patients, and in opioid-tolerant cancer patients, the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain." *Alpharma pharmaceuticals has not specifically studied the tapering of Kadian in any clinical trial, however the following information may assist you in forming your own conclusions and decisions regarding the use of Kadian.
ACTAVIS0800033	9/18/2007	Kadian Abuse and Dependence - "Addiction to opioids prescribed for pain management is rare..." "In chronic pain patients...the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain." Part of 38-doc zip drive attachment to email at ACTAVIS0799930 - 2/1/2012 - from Ntumy to Guinto-Laput containing "all the medical issue modules for Kadian"
ACTAVIS0585072	10/2/2007	Kadian Vocal Response Listing 8/29/07-10/02/07 List of data regarding calls with doctors to poll them on what Kadian sales reps told them. Examples of questions: What was the main message of the presentation; please describe the type of patients to whom you have given the cards...Same questions posed regarding Avinza formulary» «this primary care provider remembers hearing from Kadian sales rep that there is a low potential for addiction»«doctor mentions rep telling him there is a low incidence of potential for addiction» «doctor remembers the oral sustained action capsule compared to the pill

Bates #	Date	Summary
		makes it better (from a safety standpoint) for abuse» «Kadian is described as not having an addictive potential» «sales rep apparently said Kadian isn't a drug that would be posing high risk for addiction as compared to OxyContin as obvious from available data» «doctor says he prescribes Kadian because it seems to be less likely to be abused than OxyContin and that those coming in with addict.
ALLERGAN_MDL_00440906	1/15/2009	Sales Call Visual Aid Testing - Qualitative Research – is an analysis of what a group of prescribers thought of Kadian literature - demonstrates that Actavis put resources into tracking and analysing prescriber behavior and how they could utilize the knowledge to increase prescriptions of opioids and promoted the value of opioids to prescribers ALLERGAN_MDL_00440919 "More reasons for morphine" ALLERGAN_MDL_00440931 (pgs 24-26) shows they were pushing doctors to prescribe for "old knee injury" or neck pain from working at a computer.
ALLERGAN_MDL_01100743	1/27/2009	"Actavis - Kadian_Coupon_2009 _Program.pdf" - Continuation of Kadian co-pay assistance program with attached copy. Pg. 4: "Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life."
ALLERGAN_MDL_01113325	10/13/2009	"Highlights of Kadian v competition" doc touts safety and efficacy of Kadian, which has fewer peaks and valleys and is readily available on more formularies.
ALLERGAN_MDL_01113320	10/13/2009	Kadian Telesales Script -- "Call Introduction" script. It includes guidance on how to pitch Kadian to nurses and/or physicians.
ALLERGAN_MDL_00437891	4/7/2010	Latest Draft] "Managing Chronic Pain and the Importance of Customizing Opioid Treatment" "Set dose levels on basis of patient need, not on predetermined maximal dose." Also, "Opioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." "Opioids Can Be a Safer Option Than Other Analgesics," cites amongst other things, the danger acetaminophen can cause to the liver. "Improves QOL for patients, helping to maintain elevated mood, sleep, enjoyment of life, vitality, social functioning, and mental

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		health."
ACTAVIS1131491	6/16/2010	emails RE: FDA warning letter (on Kadian) In part, Actavis needs to visit approx. 10,000-11,000 physician offices to distribute corrective info. As a result Actavis is postponing sales meeting until corrective action plan is completed.
ALLERGAN_MDL_00436784	6/25/2010	Kadian Learning System, "Drug Abuse and Chronic Pain" chapter - details how until the 1980s "medical (and particularly state board of medical examiners) dogma was that the long-term use of opioids for chronic benign pain was always inappropriate. Practitioners who prescribed long-term opioid therapy, other than for cancer patients were frequently investigated and sanctioned." Goes on to detail how and when that changed, diversion became an issue. See also ACTAVIS0580642 / ACTAVIS0989088 / ACTAVIS0205095
ACTAVIS0826070	6/30/2010	Patient Information Leaflet says that "Buprenorphine hydrochloride sublingual tablets contain a narcotic painkiller that can be a target for people who abuse prescription medicines or street drugs." ACTAVIS0826071: "Buprenorphine may give you less of a 'high' than these other prescription medicines and street drugs. Withdrawal or stopping buprenorphine may be easier than stopping other prescription medicines and street drugs." ACTAVIS0826073: "You can develop dependence from taking buprenorphine hydrochloride sublingual tablets, and so you may get withdrawal symptoms when you stop taking [them]. There is also a chance that you may abuse or get addicted to buprenorphine hydrochloride sublingual tablets..."
ACTAVIS0580642	7/1/2010	"Kadian Learning System" - "It is important to recognize that tolerance and dependence do not indicate addiction. Rather, they are an expected consequence of taking opioids in moderate to high doses for a significant length of time." "Proper use of opioids is not 'maladaptive' nor does it 'interfere with the person's life'; instead, it allows the patient to return to a functional life. However, some chronic pain patients do have a substance abuse problem."

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ALLERGAN_MDL_00435944	7/6/2010	"Kadian PI Workshop - ABM Training" - "Concerns about abuse, addiction, and diversion should not prevent the proper management of pain." "Physical dependence and tolerance are not unusual during chronic opioid therapy." "Kadian provides steady blood levels of morphine sulfate with few peaks and valleys. Kadian is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection."
ACTAVIS1131482	7/7/2010	REMS PPT includes info and quotes from interviews with patients & physicians & pharmacies. These quotes/data indicate that most HCPs are not discussing many opioid risks with patients.
ALLERGAN_MDL_01173104	7/8/2010	Family of documents begins with Parent doc - Mass email amongst employees of multiple defendants. Attachments include 4 IWG REMS documents which touch upon multiple key issues in litigation including: REMS strategy, risk mitigation efforts, collaboration of defendants, Side-by-side comparison of the FDA REMS proposal vs. IWG proposal, medication guides, form letters to medical personnel, training guide for prescribers, safety information, and Cover letter to FDA re: industry working group draft REMS.
ACTAVIS0580066	7/31/2010	Letter to Healthcare Professional re: Correction of Drug Information about Kadian; specifically as it relates to FDA's Warning Letter. In the Warning Letter, FDA raised the following concerns regarding the material: (1) it omitted and minimized serious risks associated with KADIAN; (2) it broadened KADIAN's indication and failed to present limitations to its approved indication; and (3) it presented unsubstantiated superiority claims. Upon receiving this letter, Actavis immediately ceased using or distributing this material.
ALLERGAN_MDL_00435558	8/3/2010	"Corrective Message Training Kadian Field Sales Team" - One of the ways Actavis responds to FDA warning letter re: misleading promotional materials is by providing additional training to sales. Do not make unsubstantiated effectiveness claims.
ALLERGAN_MDL_00435541	8/6/2010	Actavis template for corrective letter to HCPs

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		in which they admit to downplaying risks, giving over-broad description of drug indications, and making unsubstantiated claims of superiority to other pain relieving drugs.
ALLERGAN_MDL_00435403	8/19/2010	"Kadian Corrective Information Rollout - Training Class InVentiv Health" - Detailed plan for sales force and Actavis to communicate key corrective messages to those who have been exposed to Co-Pay Assistance Program Brochure.
ALLERGAN_MDL_00434909	12/29/2010	"Marketing Overview, Jennifer Altier" "Kadian Message: Safety - Leverage HCP perception of Kadian's safety profile to gain new Rxs as well as to position Kadian as a viable alternative when patients are dissatisfied with the new formulation of Oxycontin. Kadian has a well known safety profile. No product in the LAO class has a label supporting an abuse-deterrence claim."
ACTAVIS0978471	12/31/2010	"Clarifying the Top Objections to a Kadian CapsulesPresentation" - "Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs." *For Internal Training purposes Only
ACTAVIS0367358	4/20/2011	- Cold call script Financial targeting relying on Medicare, see pg. 3 ACTAVIS0367358 at -7360 Instructions to tailor responses to questions as stirring away from any negative or risk awareness. Fair Balance is for the end of the conversation or when they send materials - this leaves open for sales reps to neglect to close with risks.
ALLERGAN_MDL_00643116	4/22/2011	Final Proposal for Risk Minimization Action Plan. ALLERGAN_MDL_00643115 email sending it from Annechino to Nataline. At ALLERGAN_MDL_00643147 - SOAPP (Screener and Opioid Assessment for Patients with Pain) measure helps determine how much monitoring a patient on long-term opioid therapy needs. "Scoring system" approach. At ALLERGAN_MDL_00643151 - info. about Current Opioid Misuse Measure At ALLERGAN_MDL_00643173: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that

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		are prescribed for them."
ALLERGAN_MDL_00681039	4/25/2011	- Email chain between Rebeco, Plassche, Young, Aprahamiam and others. Rebecco reports that DEA responds to oxycodone quota request with much less than requested - DEA request was due to distribution to illegal market, with people dying monthly in Kentucky – Michael Perfetto says that they "may need to spin this with customers." Aprahamiam agrees on "spin" but says "don't upset the balance" on pushing for additional approval.
ALLERGAN_MDL_00664891	5/9/2011	David Brown asks Paul Coplan for "high-level 'minutes' of key decision points and action items, to memorialize them in writing. "That way, we can systematically inform our internal company colleagues of our decisions and approach before the May 12 FDA prep meeting without contradicting ourselves." Allergan_MDL_00664896 - 5/9/2011 - LAO REMS, including Actavis.
ALLERGAN_MDL_00641753	5/23/2011	Email between Nataline and Fridriksdottir discussion on the need to develop a "life-cycle strategy" for Kadian's new strengths.
ACTAVIS0823350	6/2/2011	Emails regarding marketing and development of new strengths: "...the 30 mg is the biggest seller (units) but the 100 mg makes the most sales dollars."
ACTAVIS0361609	6/28/2011	Qualitative Research Interviews - "Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids." See also ACTAVIS0192847 - 3/8/2013 - Kadian Marketing Update
ALLERGAN_MDL_01040653	6/30/2011	"Oxymorphone Hydrochloride ER Tablets - Generic is Now Available" - Electronic Sellsheet. "Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts."
ALLERGAN_MDL_00401004	7/31/2011	Oxymorphone Sales Training Comes following the 2010 FDA warning on Kadian, and looks like emphasis on training that includes problems with opiates. However, the focus is

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		on brand availability with a cursory, obligatory mention of risks. See pg. 13, at -1016. "Limit conversations regarding the indication of the product or defer to medical affairs as this is not intended to be a risk/benefit discussion. This is merely an availability announcement." See pg. 14, ALLERGAN_MDL_00401017
ACTAVIS0335906	11/17/2011	email from Atlier to DeSantis and Leitch - attached is ACTAVIS0335915 - Kadian generic telescript which saysthat it provides steady blood levels with few peaks and valleys, no ceiling or maximum dose. Also relevant to long-acting/abuse deterrent issues.
ACTAVIS0335906	11/17/2011	attachment at ACTAVIS0335908 - - Email from Altier to DeSantis and Leitch attaches Kadian generic telescript, which says that it provides steady blood levels with few peaks and valleys, no ceiling or maximum dose.
ACTAVIS0799930	2/1/2012	Email from Ntumy to Guinto-Laput, Thapar, Fogelson attaching "all the Medical Information Modules for Kadian." ACTAVIS0799986 - 2/1/2012 - One of the attachments titled "Kadian and Tapering of Opioids" says that "Addiction to opioids prescribed for pain management is rare..." and "In chronic pain patients...the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain."
ALLERGAN_MDL_00441731	2/21/2012	Prescriber feedback on sales presentations. Many prescribers report that sales rep said Kadian is safe and that addiction/abuse potential is low. Prescribers also report that sales reps compared Kadian to other drugs.
ALLERGAN_MDL_ 00048337	7/17/2012	"Kadian Marketing Overview - Sales Representative Training" [similar doc from 10/31/2011] - Kadian does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy."
ALLERGAN_MDL_ 01286709	8/29/2012	"NSAIDs and Anti-Inflammatories" Deborah A. Ward, PharmD., BCOP, BCPS - Presentation detailing safety, efficacy, and risks involved in treating pain with NSAIDs and Acetaminophen (despite title). Parent email

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		from Ivan Shaw to Jeannette Barrett.
ACTAVIS0841944	8/30/2012	email attaching American Pain Foundation's Pain Week slides. ACTAVIS0841958 / ACTAVIS0841977 – suggests opioid treatment for pain management without offering other substantive options; says addiction occurs in only 3% of chronic pain patients
ACTAVIS0841616	8/30/2012	"Intellectual Honesty and Dishonesty in Opioids for Chronic Pain Management" Presentation touches on several key issues including overstating benefits and downplaying risks, "what is functional improvement?", and "misapplication of pseudoaddiction" (calls it "poor scholarship").
ACTAVIS0841633	8/30/2012	REMS update slides from PainEDU.org, one of many attachments to email from Ivan Shaw to Jeannette Barrett at ACTAVIS0841424 ACTAVIS0841635 Describes the impacts of the "Far-Reaching Public Health Impact of Widespread Opioid Analgesic Abuse/Misuse" mental impairment, unintentional injuries, family stability infections and other health effects. Also relevant to Low Risk of Addiction/Easily monitored ACTAVIS0841636- 8 shows the increasing rate of nonmedical users, state that teens erroneously think that these drugs are safer than "street drugs" - describe "increasing" addiction and diversion problems. (same family) ACTAVIS0841454 Slides re The Rational Use of Opioid Analgesics for Non-Cancer Pain: What Every Prescriber Needs to Know» Disclosures include Charles Argoff as consultant/Independent Contractor for Grunenthal, Depomed, Grant/Research Support from Endo, Honoraria from Depomed, Endo, Janssen, and Speakers Bureau from Endo and Janssen, Reference to APS/AAPM Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain Pseudoaddiction definition.
ACTAVIS0842077	8/30/2012	Pain Week Slides "When does Acute Pain Become Chronic" indicates that opioids decrease functionality, and might even cause chronic pain or further injury.
ACTAVIS1137030	8/31/2012	Email from sales manager to Marketing Director/Manager Jennifer Altier with

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		compilation of marketing suggestions from sales reps of the "West Region". It seems that the sales reps believe that many doctors' offices and possibly pharmacies are confused on Kadian dosing and/or Generic dosing.
ACTAVIS0575027	9/13/2012	Kadian Marketing Update: market research shows doctors believe Kadian has low abuse potential and have "comfort in prescribing to suspected alcohol abusers due to lack of potency loss." See also ACTAVIS0003354 Kadian Marketing Update; dated 9/13/2012 Perception of low abuse potential, targeting elderly. Objection Handling - also shows composite use of conversations with doctors.
ALLERGAN_MDL_00802760	9/13/2012	"Kadian Access Strategy" - Improving access to coverage, including "adding 4 strengths to the 31 preferred drug lists where Kadian is currently covered."
ACTAVIS0228068	9/28/2012	family/attachment: ACTAVIS0228070 - - Kadian website information indicates risk of abuse and addiction - C discusses withdrawal symptoms, says "physical dependence is not the same as drug addiction."
ACTAVIS0690598	10/2/2012	"Kadian and Abuse Potential" is "A guide for prescribers under Actavis' copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." Abuse potential is apparently less because of (a) slow onset of action (b) lower peak morphine levels than equivalent doses of other formulations of morphine (c) longer duration of action (d) minimal fluctuat…
ALLERGAN_MDL_ 00219529	10/18/2012	Kadian Access Strategy Update. This document discusses strategy and tactics for managed care/Medicare.

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ACTAVIS0997492	12/13/2012	Quantitative Testing of Prescriber Knowledge, Attitudes, and Behavior about Extended Release and Long Acting Opioid Analgesic Products safety and use info.
ACTAVIS0197875	2/18/2013	Sales Training Presentation focuses on benefits of Kadian and instructs on how to deal with "objections" from prescribers , mentions "co-pay assistance." ACTAVIS0197874 email from Altier to Killion, to which Presentation is attached.
ACTAVIS0197923	2/18/2013	family at ACTAVIS0197924 - - Kadian Marketing Overview - no "ceiling" on dose, advises to increase until therapeutic endpoint reached or "clinicallysignificant opioid-related adverse reactions intervene."
ACTAVIS0193441	3/5/2013	"Kadian PI Workshop" - "Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors)."
ACTAVIS0192847	3/8/2013	Marketing Presentation - "Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids." See also ACTAVIS0361609 12/2010 Marketing.
ALLERGAN_MDL_00992106	3/8/2013	This document touts the dosage flexibility of Kadian. It is flexible because of its BID ("bis in die," which means twice a day) and QD ("quaque die," which means once a day). The dosage can be sprinkled on applesauce and should not be abruptly discontinued for those with a physical dependence on the drug.
ALLERGAN_MDL_00992106	3/8/2013	Kadian Sales Training Presentation - lists the goals of chronic pain management, one of which is "to improve the patient's sense of well-being."
ALLERGAN_MDL_00005223	3/8/2013	Family at ALLERGAN_MDL_00005225 – Actavis slideshow examination of "pain market" - states "there is no strong branded product in our current portfolio to serve as the foundation for the pain franchise" SWOT analysis identifies environment encouraging prescribers to write fewer opioids, proposed rescheduling of Norco as threats, says tamper-resistant products are physicians' #1 wish.

Bates #	Date	Summary
ALLERGAN_MDL_00750772	3/8/2013	AVIS0580066Part of family beginning with email at ACTAVIS0192811 from Leitch to Gallagher re: materials for Sept meeting, most notably sales training and tactics.
ALLERGAN_MDL_ 00993613	4/25/2013	"The Nervous System" - Appears to be an Actavis speaker presentation. Tolerance and Dependence. Drug loses its effectiveness with repeated use; higher dose required to produce same analgesic effect. Management is to increase dose and/or frequency of administration; Combine opioid and nonopioid to achieve additive analgesia without increasing opioid dose; Slowly taper dose by 10% to 20% every other day to manage physiological dependence. *Confidential for training purposes only.
ACTAVIS1011873	5/9/2013	section 4.3.1 is Call Center Activities showing collection of data from doctor calls re Email to people from several different organization re: REMS team meeting minutes/materials.
ACTAVIS1011873	5/9/2013	Email to people from several different organization re: REMS team meeting minutes/materials. Attachment at ACTAVIS1011900 - Testimonials, in a blog-type platform, discuss adverse events, addiction – including with no prior history of abuse, horrible withdrawal/insomnia, dissolving, injecting. Mentions "addiction doc"(tors) in contrast to pain doctors.

Additionally, pursuant to FRCP 33(d), Plaintiff identifies the following documents:

PURCHI-003286781

PURCHI-003286781

PURCHI-003286781
PURCHI-003286781
ABT-MDL-KY-0001668
PURCHI-003286781
PURCHI-003286781
ABT-MDL-KY-0024177
CHI_000169914
PURCHI-003286781
PURCHI-003286781
CHI_000169914
ABT-MDL-KY-0024177

PPLP004033318
PURCHI-003286882
CHI_000169914
CHI_000169914
PPLP004030463
PURCHI-000675080
PURCHI-000679205
PURCHI-000675080
PURCHI-000675080
CHI_000169914
PPLP004086124
PPLP003549472
PPLP004033318
PPLP003996972
PPLP003420538
PPLP004001344
PPLP004001344
PPLP003420538
PPLP003344295
PPLP003344860
PPLP03344860
PPLP003344932
PPLP003420448
PPLP003461097
PPLP003420572
PPLP003420538
PPLP003420538
PPLO003461097
PPLP003420538
PPLP003409899
PPLP003409457
PPLP004001344
PKY1738102062
PPLP004033318
PDD1712900035

Date	Document	Summary
2000	Actiq 2000 Master Plan, (TEVA_CHI_00042757) (Doc. 227).	Actiq master plan noting regulatory oversight as key hurdle in Actiq's success, need to market to pain management specialists who are likely to be aggressive adopters of Actiq, and the weakness of a limited indication and need to expand that indication.
2003	Actiq 2003 Marketing Plan, (TEVA_MDL_A_00454872)	2003 marketing plan outlines current market dynamics, SWOT analysis and key marketing issues,

Date	Document	Summary
	(Doc. 229).	the Actiq vision, marketing and promotional strategy, and the core Actiq tactical plan, including target audience.
2004	Actiq 2004 Marketing Plan, (TEVA_MDL_A_00454872) (Doc. 230).	Similar to 2003 marketing plan; outlines current market dynamics, SWOT analysis and key marketing issues, the Actiq vision, marketing and promotional strategy, and the core Actiq tactical plan, including target audience.
4/30/2004	FDA Meeting Minutes FDA Accuses Cephelon of Off Label Promotion, 4/30/2004, (TEVA_MDL_A_00505359) (Doc. 302).	Key document showing FDA accusation against Cephalon regarding use of sales force for off-label marketing (p. 360) and criticism of how they market for break-through pain for non-cancer patient specialties.
2005	Actiq 2005 Marketing Plan, (TEVA_MDL_A_00455000) (231).	2005 Marketing Plan shows that Teva is still actively marketing to non-cancer areas as evidenced by Teva's PDE's (Primary Detail Equivalent), which is a detail that is in the first position (i.e., no other product receives more emphasis or focus) in a sales call by a pharmaceutical sales representative (see Slide 4).
5/24/3018	Teva Defendants - Responses to Request for Production, 5/24/2018, (TEVA_CHI_00016437) (Doc. 226).	Responses and Objections of Cephalon, Teva, and Actavis to Plaintiffs' First Set of Requests for Production of Documents.
2005	OraVescent Fentanyl (OVF) Commercial Strategy Meeting 2005 PP, (TEVA_MDL_A_00373479) (Doc. 263).	The Commercial Strategy Powerpoint illustrates Teva's approach to commercialization, specifically "creating the need" and selling to that need.
9/26/2005	PMEAB 2005 FEBT Marketing PP, 9/26/2005 (TEVA_MDL_A_00399532) (Doc. 276).	FEBT Marketing Powerpoint shows how Teva continued to market to non-cancer patients.
2006	Pain Medicine 2006 Year-End Report, (TEVA_MDL_A_00564864) (Doc. 285).	2006 Year-End Powerpoint presentation shows Teva had awareness of their off-label marketing and sales practices relating to breakthrough pain, expanding further than their indication for breakthrough cancer pain.
2006	Clinical Management of Breakthrough Pain 2006 PP, (TEVA_MDL_A_00009053) (Doc. 286).	Presentation that encourages market growth by marketing to the symptom (i.e., pain) and not the disease (i.e., cancer) (see Slide 2 and Slide 3).
2006	Actiq 2006 End of Life Cycle Plan, (TEVA_MDL_A_00366691) (Doc. 228).	Discusses end of life-cycle for Actiq due to generic erosion, and outlines key issues and critical success factors for opioid launch after Actiq patent expiration.

Date	Document	Summary
2006	Actiq Marketing Executive Committee 2006 Update, (TEVA_MDL_A_00366344) (Doc. 288).	Actiq market committee report from 2006 showing prescription trends, including charts showing that only 7% of prescriptions came from oncology practices (see Slide 8).
8/8/2006	Email re June Ranking Report, 8/8/2006 (TEVA_CHI_00004942) (Doc. 154).	Randy Spokane email discussing June 2006 sales ranking report, and need to continue driving Actiq sales until the day Fentora is launched.

Date	Document	Summary
2006-2011	Ohio Sales Call Run Document, (TEVA_MDL_A_00763717) (Doc. 319).	Approximately 250-page spreadsheet showing detailing calls made in Ohio by Teva Sales representatives, providing product, sales representative name, and health care provider's name and address.
N/A	Amrix Speciality Code Description Chart, (TEVA_MDL_A_00700492) (Doc. 320).	Spreadsheet providing specialty code descriptions used to categorize physician specialties by sales representatives. Includes non-cancer specialties throughout the spreadsheet.
2006	1st Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00038512) (Doc. 166).	1st Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives. Shows that Tier 1 sales representatives will be paid $0.09 on every dollar of sales generated over the 1st quarter quota up to a maximum payout of $9,000, and Tier 2 will be paid $0.07 on every dollar of incremental sales generated above the Tier 1 maximum. The target bonus was $11,250.
2006	4th Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00038518) (Doc. 167).	4th Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives. The target bonus for Fentora launch is $11,250 based on two components: (1) Fentora retail prescription dollars, DDD non-retail, and DDD mail-order dollars; and (2) Fentora DDD retail pharmacy dollars, DDD non-retail, and DDD mail-order dollars.
3/2013	J Natl Compr Canc "Guidelines for the Management of breakthrough Pain in Patients with Cancer," 3/13, (Doc. 282).	Journal article titled, "Guidelines for the Management of Breakthrough Pain in Patients with Cancer," discussing a comprehensive pain management approach that addresses the various presentations of pain in patients with cancer.

		Defines breakthrough pain as "transitory exacerbations of pain that occur on a background of stable pain otherwise adequately controlled by around-the-clock opioid therapy." Concludes that all "evidence-based guidelines on managing idiopathic breakthrough pain in cancer include rapid-acting opioids as a treatment option, most of which also include fentanyl formulations." Further notes that it is important "not to overuse rapid-acting opioids for pain that could be managed with around-the-clock opioid titration and with the careful and well-established use of immediate-release oral opioids or other therapeutic strategies."
2006	4th Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00039257) (Doc. 162).	4th Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives. States that total Fentora 4th quarter 2006 target bonus is $12,000, based on 2 components: (1) Fentora retail prescription dollars plus non-retail and mail-order DDD dollars; and (2) Fentora DDD retail pharmacy dollars plus non-retail and mail-order DDD dollars.
6/2006	June 2006 Pain Care Specialist Ranking Report, 6/2006, (TEVA_CHI_00004943) (Doc. 154).	Email from Randy Spokane attaching June sales ranking report, and also noting the top sales representatives. Notes that as the lifecycle of Actiq begins to near its end, sales representatives must remain focused on driving sales until the day Fentora is launched. Notes that Alex Burlakoff and the Southeast Team finished #1 in Q2. Also recognizes Kelli McKenzie, David Savitt, Lisa Pacin, Karen Hill, Beth Aronica, Sly King, and Matt Morreale as top sales representatives.
2009	3rd Quarter 2009 Incentive Compensation Plan, (TEVA_CHI_00038572) (Doc. 164).	3rd Quarter 2009 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives. States that the target Fentora 3rd quarter bonus is $2,625. Further explains that "For 3rd quarter 2009, your Sales Base will be the average of 1st quarter 2009 and 2nd quarter 2009. This Sales Base

		will be used to calculate your Target Quota. If your 3rd quarter 2009 sales equal your Target Quota you will earn the Target Bonus of $2,625. In addition, you will be paid $0.5 for every sales dollar you generate over your Target Quota."
2012	2012 Memo re Fentora REMS, (TEVA_CHI_00004423) (Doc. 152).	Memo stating that on "March 13, 2012 the Fentora REMS will officially be locked-down" so there "are only (14) selling days remaining to enroll Health Care Providers (HCPs) AND earn significant bonus for your efforts."
7/1/2012	Fentora Targeting Assessment and Call Activity Document, 7/1/2012, (Doc. 324).	Targeting assessment and call activity memorandum discussing policy details regarding targeting assessments, sales representative call activity, do not compensate (DNC) specialties, one-time calls on DNC specialties, and monitoring. Specifically states that "Teva only promotes its products to those HCPs when it is reasonable to believe that his or her practice includes patients that could be treated with a Teva product for an on-label indication." Also states that "[s]ales calls do not include e-mails, text messages, faxes or telephone calls to HCPs."
7/25/2018	Komal email re Top 100 Prescribers, 7/25/2018, (Doc. 334).	Email identifying Top 100 providers and "do not call" providers. Notable top 2010 prescribers include Louis Spagnoletti, who was temporarily barred from treating patients by NJ's AG for indiscriminate prescribing, Gordon Freedman, who was indicted for receiving kickbacks, and Charles Brown, a nurse practitioner convicted of conspiracy to distribute opioids including fentanyl at a pill mill.
12/2005	Fentora Marketing Plan 2005-2006, (TEVA_MDL_A_00368405) (Doc. 270).	2005 FEBT (Fentora) marketing plan discussing transition of physicians from Actiq to Fentora. Provides market and competitor assessments, and a SWOT analysis. Also notes critical success factors and key issues. States that key issues include "low understanding of diagnosis and treatment of breakthrough pain (BTP)," "limited KOL, society, and MCO relationships," and "concern for abuse, addiction, & diversion."

		Critical success factors for Fentora include "expand KOL, society & MCO relationships," "minimize abuse, addiction, & diversion," and "converting Actiq loyalists within 90 days." Also discusses the "challenging selling/marketing environment requiring sophistication and expertise." Specifically notes that "the FDA requires all newly approved schedule II opioid products to implement a comprehensive Risk Minimization Plan" which will "contribute to the difficulty and complexity of selling/marketing a CII medication." "Another complexity is that the undertreatment of pain continues to be a widespread problem. It has been postulated that one reason why pain is undertreated is physician fear of prescribing opioid analgesic medications (i.e., opiophobia). This fear is mostly attributed to concerns of abuse, addiction, and diversion, as well as scrutiny by regulators that monitor the prescribing and dispensing of these medications." Cites to Portney's breakthrough pain study, stating "Portney's BTP survey identified … that there is a need to study BTP therapies in areas beyond cancer – in particular in back and neuropathic patients" because the "prevalence of cancer-pain patients is significantly less than non-cancer pain patients." One strategy to minimize risk for abuse, addiction, and diversion was to "negotiate optimal RiskMAP to meet standards and minimum risk without compromising appropriate use and opportunity," as well as "educate patients about safe use of FEBT and allay fears of opioids."
	Fentora FAQs and Suggested Responses, (TEVA_MDL_A_00394119) (Doc. 172).	Fentora frequently asked question responses regarding abuse, addiction and diversion and minimizing risks associated with Fentora to properly market. Sales aid states that appropriate patients are: • Regularly taking around-the-clock (ATC) opioid regimens to control persistent pain • Considered opioid tolerant

		• Cancer-related chronic pain • 1 to 4 episodes of BTP per day Also notes that "FENTORA contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. FENTORA can be abused in a manner similar to other opioid agonists, legal or illicit." "Cephalon believes that a proactive approach to communicating the potential risks of opioid analgesics is a key component of minimizing risks. As a result we have developed a comprehensive 3 primary objectives of the SECURE Program: 1. Ensure that patients and healthcare professionals understand that FENTORA should be used only by opioid tolerant patients with cancer 2. Minimize the potential for misuse, abuse and diversion of FENTORA 3. Minimize unintended or accidental exposure to FENTORA"
2006	Fentora 2006 PP "A Change is Coming...Effervescent Speed," (TEVA_CH_00004953) (Doc. 155).	2006 Fentora launch powerpoint. Notes that target audience for Fentora is "healthcare professionals", and also discusses voucher program (i.e., 75 vouchers per rep for Q4). Also notes that generic opioids are a threat. Slide 16: Provides Fentora's Clinical Plan, including breakdown of Cancer studies and non-cancer breakthrough pain studies, with publication plans for each. Slide 10: Lists "Direct Selling Tools for Launch" including "Patient FAQ Brochure, Administration Tear Sheet, Medication Guide, Placebos, Patient Starter Kit."
2006	Oravescent Fentanyl (Fentora) 2006 Pre-Launch and Launch Plan PP, (TEVA_MDL_A_00008300) (Doc. 267).	Fentora pre-launch and launch plan. Slide 14 shows that Cephalon has the opportunity to "[c]hange the perception of BTP and increase awareness for appropriate treatment (RAO)." However, the weakness is that the "[l]abel is limited at launch to BTP in cancer." And Cephalon notes as a threat to profits "increased regulatory scrutiny and media attention.".

		Slide 45 discusses "using PR to shape opinion." In particular, Cephalon wanted to "repair the opioid category image – put the abuse potential into perspective versus "patient abuse" resulting from untreated pain.". Slide 33 shows Cephalon's plan to "Expand into Nonmalignant Pain," including "continue to develop clinical evidence supporting broader use of [Fentora]" and "expand investment in the chronic pain management category.". Slide 50 shows how Cephalon planned to "ally with employers/unions" and "focus on large, often self-insured, enterprises that employ workers who can be marginalized by BTP," including "construction," "transportation," and "civil service." Discusses how breakthrough pain is "open to interpretation", but must be precisely defined. Cephalon wanted to link "BTP inextricably to unpredictable, rapid & intense BTP."
	GlenGarry Glen Cephalon, (TEVA_MDL_A_00404021) (Doc. 277).	Breakthrough pain and Fentora sales script based off GlenGarry Glen Ross monologue, stating how sales reps need to "close or hit the bricks." "You think they want to write Percocet? The doctors don't prescribe unless you close them. They're sitting out there waiting to give you their money. Are you gonna take it? Are you going to exceed quota?" "These are the Fentora targetrs. And to you, they're gold." "Man o'Man am I motivated to get out there and sell Fentora!"
2006	Clinical Management of Breakthrough Pain 2006 PP, (TEVA_MDL_A_00009053) (Doc. 286).	2006 Breakthrough Pain PowerPoint presentation. States that "Cancer pain [vs] noncancer pain...Categorization by disease is less important than pain pathophysiology." This PowerPoint presents many patient profiles who are "eligible" for opioid treatment, most of whom are not cancer patients.

		Slide 2 notes that "Noncancer ≈ Cancer" and that categorization by disease is less important than pain pathophysiology. Slide 24 reinforces need to minimize risks for abuse, misuse, and diversion. Slide 57 discusses "Barriers of Optimal Opioid Use" including: abuse and addiction concerns; confusion (physical dependence, tolerance, addiction)." It also notes consequences of addressing the limiting factors including: pain undertreated; potential stigmatization despite the legitimate opioid use. Slide 58: All Addicts are Abusers, But Not All Abusers are Addicts Slide 60: Unresolved issues – Patient selection – Appropriate dosing – Patient monitoring – Problematic patients Slide 102: Concluding Comments: Cancer and noncancer BTP require similar analgesic approaches; BTP adversely affects QoL and function in cancer and noncancer patients.
8/9/2006	Fentora Launch Planning 2006 Update, (TEVA_CHI_00005721) (Doc. 241)	Fentora Publication Plan showing intent to publish both cancer and non-cancer studies from 2005 to 2007. Also provides summary of marketing priorities for Fentora launch. Notes key accomplishment as publication of Portneoy's non-cancer breakthrough pain survey published in J Pain. Sets priority for "development of CephalonSpeaker.com website to support Fentora." Outstanding issue noted is the "finalization of revised RiskMAP for submission to FDA." Slide 14 discusses use of Fentora for non-malignant chronic pain in opioid-tolerant patients.

9/25/2006	Memo re Cephalon Receiving FDA Approval of Fentora for the Management of Breakthrough Pain in Patients with Cancer, (TEVA_CHI_00005323) (Doc. 156).	Fentora Press Release stating that "Cephalon Receives FDA Approval of FENTORA for the Management of Breakthrough Pain in Patients with Cancer."
2007	"Weighing in on the Off-Label Use of Actiq for Noncancer-Related Pain; A Recipe for Success or a Recipe for Disaster?" 2007, (Doc. 221).	Article regarding off-label Actiq use written by Cephalon Speaker Bureau member. "Our longer-term clinical strategy is focused on developing FENTORA for patients with breakthrough pain associated with other conditions, including neuropathic pain and back pain."
2007	Fentora 2007 Marketing Plan, (TEVA_MDL_A_00398243) (Doc. 264).	2007 Fentora Marketing Plan. "Growth Inhibitors:-scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids" "Key environmental trends-Social/cultural: Abuse and diversion are top-of mind topics for physicians and other stakeholders, Political/governmental: Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids, FDA is hypersensitive about safety issues" Fears for Physician: Patient abuse, addiction, & diversion of opioids, Regulatory scrutiny. Fear for Patients: Addiction (loss of independence), Over medication (sedated / confused), Running out of opioids (rationing), Anxiety over severity and timing of next breakthrough pain episode (unpredictability), Physicians will stop prescribing opioids. Slide 33: Growth Drivers: Aging baby boomers and growing US population will increase the size of the chronic pain patient population; Increase in treatment of chronic pain with opioids; Pain Specialists are more aggressive in treating chronic pain; More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume; Increasing understanding about the proper identification, diagnosis and

		treatment of BTP; New competitive entries Growth Inhibitors: Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids; Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids; Chronic pain practice standards (especially for BTP) are still evolving; Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]; Perception by some physicians that SAOs are a preferred treatment option for BTP based on familiarity, ease-of-use, and cost. Slide 76 notes the Fentora SWOT Analysis: Strengths: Published Data in non-cancer BTP Weaknesses: Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study, perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg) Slide 77 continues the Fentora SWOT Analysis: Opportunities: Aging population Threats: Limited understanding of BTP and its appropriate management outside a small community of pain specialists, fear of abuse and diversion with opioids, increasing government restrictions on C-II opioids Slide 80 sets out the FENTORA mission of establishing FENTORA as the gold standard for breakthrough pain. Slide 96 discusses issues and strategies for Fentora.

		Issue: Risk for abuse, addiction, and diversion Strategies: Educate HCPs on appropriate patient selection, educate patients about safe use of FENTORA and allay fears of opioids, continue to implement risk minimization tools, maximize SECURE outreach program initiatives
2008	Competitive Intelligence 2008 Report, (TEV_FE00002696) (Doc. 236).	2008 Internal memo discussing competitive intelligence priorities, and need to develop competitive blunting strategies.
2008	Fentora 2008 Brand Plan, (TEVA_MDL_A_00370019) (Doc. 290).	2009 Marketing Plan. Examples of distinction between Cancer BTP and Noncancer BTP. Goal is to establish BTP as a disease state. Providers SWOT analysis, and key issues, as well as publications plan and public relations plan (see App. A and B). Slide 33: Notes key environmental trends-Social/cultural. States that "[a]buse and diversion are top-of mind topics for physicians and other stakeholders. Also notes key political/governmental trends including "opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids; FDA is hypersensitive about safety issues." Slide 35: Growth Drivers: Aging baby boomers and growing US population will increase the size of the chronic pain patient population; Increase in treatment of chronic pain with opioids; Pain Specialists are more aggressive in treating chronic pain; More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume; Increasing understanding about the proper identification, diagnosis and treatment of BTP; New competitive entries. Slide 83: Put forward Fentora SWOT Analysis: Strengths: Published Data in non-cancer BTP Weaknesses: Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study, Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)

		Slide 84: Fentora SWOT Analysis: Opportunities: Aging population Threats: Limited understanding of BTP and its appropriate management outside a small community of pain specialists, fear of abuse and diversion with opioids, Increasing government restrictions on C-II opioids
7/2/2008	Fentora 2008 Marketing Overview PP for Megaffin, 7/2/2008, (TEVA_MDL_A_0037524) (Doc. 271).	2008 Fentora Marketing Powerpoint. Slide 7 shows chronic pain prevalence, diagnosed and treated by underlying conditions. Cancer has the lowest prevalence, lowest diagnosis, and lowest treatment. Meanwhile, arthritic pain is the highest, with neuropathic pain a close second. Back pain is third, but represents approximately 9 million more patients than cancer pain. Slide 22 shows graph with back pain as the most treated condition with Actiq, followed by neuro, headache, cancer, and arthritis. Back pain represented 38% of underlying conditions treated with Actiq. Slide 34 shows Fentora's "potential for abuse" as a barrier based on physician perceptions, and that it is a "potent opioid (held in reserve)." Slide 36: "Threats: Risk for abuse and diversion...Critical success factor: Minimize risk for abuse and diversion" Slide 41 shows a bar graph illustrating the percentage of underlying conditions treated with Fentora. Cancer represents only 18%, while back pain is 20%, neuro is 12%, and other pain is 27%.
7/11/2008	Fentora Critical Success Factors (CSF), 7/11/2008, (TEVA_MDL_A_00376298) (Doc. 157).	2008 Fentora Marketing Powerpoint discussing Fentora's critical success factors. The highest rated issue facing Fentora is "Achieving broad acceptance of BTP (breakthrough cancer pain) (both CA and non-CA) and need for ROO (rapid-onset opioid) solution in light of broad array of LAO/SAO options."

		Another key issue for Fentora is the "perception of increased risk of abuse with ROO (rapid-onset opioids) products." Included on Fentora's list of critical success factors are: "greater awareness of BTP & acceptance of ROO," "clear & consistent communication of Fentora risks," "differentiated from competitors," and "patients have access to reimbursement similar to Actiq at peak." One of the key strategies for differentiating Fentora was to "successfully bring to market a non-CA BTP indication." Cephalon also planned to "use the non-ca label expansion to accelerate awareness and trial," and also "secure better support from pain societies." With regard to the key issue of risk for abuse, addiction, and diversion, Cephalon states "TBD." "Issue: Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; Critical Success Factor: Physicians and patients have a greater awareness of BTP and accept ROOs as ideal treatment; Strategies: Develop an unbranded disease state awareness campaign focused on CA BTP, which could efficiently evolve into a broader BTP campaign upon securing a label expansion. Bridge the communication gap between patients and physicians by creating a common language. Develop a burden of illness story to strengthen the need/importance of effectively addressing BTP"
2009	Fentora 2009 Brand Plan, (TEVA_MDL_A_00398245)(Doc. 275).	2009 Fentora Brand Plan. "One barrier to successful management of chronic pain with opioids is concern associated with abuse, addiction, and diversion." "Market drivers: Increase in number of chronic pain patients continues to drive opioid sales. Market Threats: Concern persists for abuse, addiction, and diversion." Cephalon noted key challenges with their

		RiskMAP, SECURE, including " 15% to 40% of patients on Fentora may not meet the strict definition of opioid tolerance defined in the label," "sales force will be integral in driving enrollment and participation," and "approval of the expanded label is contingent on documenting the effectiveness" of the RiskMAP Cephalon sought to "obtain expanded label after REMS [was] shown to be effective," as well as "[s]ubmit high dose after REMS [was] shown to be effective."
2010	Fentora 2010 Program Review/Website Promotions, (TEV_FE00030646) (Doc. 237).	2010 extensive summary of marketing material for Fentora. Includes PDR sponsorship, specifically sponshorship of the 2010 Pain Management Prescribing Guide. Cephalon conducted a breakthrough pain workshop for pain management specialists. Also includes payment stubs from shareyourpain.com -- a support website for those with severe pain and other online tools such as a "digital pain tracker" where patients can record frequency of pain to show their doctor. Cephalon also provided nurse counseling kits designed to help them educate patients on breakthrough pain, Fentora, and the SECURE (RiskMAP) program.
2009	Fentora 2009 Brand Plan, (TEV_FE00037945)(Doc. 240).	2009 Fentora Brand Plan. Situation Analysis, marketing strategy, and marketing expenses. Provides summary of key 2008 market issues (i.e., limited understanding of breakthrough pain) and 2008 key strategic imperatives (i.e., greater acceptance of breakthrough pain). The brand plan also provides the 2008 Fentora expense budget, which includes a total budget of $15,175,000, with 5.75 million allocated for advertising promotional materials, 2.7 million allocated for field driven speaker programs, 1.8 million allocated for medical education, 1.3

		million for meetings, conferences, Congresses, conventions, and exhibits, and 1.2 million allocated for samples and debit card program. 2009 challenges for Fentora include "REMS/Registry logistics," "reimbursement hurdles," and "concerns for abuse misuse, and diversion." Page 28: Outlines opportunities, including: Aging Population; Lists threats as "safety concerns for abuse and diversion." The 2009 sales goal was $175m total revenue, and 76,334 TRx's.
2010	Fentora 2010 Brand Plan, (TEV_FE00030805) (Doc. 238).	2010 Fentora Brand Plan. Discusses need to optimize BTP treatment, particularly with rapid-onset opioids, such as Fentora. States that there is "limited opioid REMS awareness, acceptance and endorsement by HCPs." The "prescriber base is not REMS savvy" and there is a "perception of increased burden to HCP and office staff." Cephalon wanted "to see Fentora considered earlier in the treatment algorithm" because "ROOs (rapid-onset opioids) are considered only after" LAOs or SAOs. 2010 key promotional tactics include "ShareYourPain.org" and "unbranded website to educate patients on the components of chronic pain."
2011	Fentora 2011 Brand Plan, (TEVA_MDL_A_00556008) (Doc. 279).	2011 Fentora Brand Plan. "Strengths: Precise/Not over-medicating; Flexibility to re-dose/Delivery matches pain; Fast and powerful; Reliable and predictable; Permits patient functionality; Bright future - Pipeline; Heritage - Well-studied/Proven; REMS as safety net...Weaknesses: Expensive/Lack of coverage - weak Cost vs. Value perception; REMS is viewed as a hassle; Misunderstood - across all stakeholders; Limited peer influence - HCPs and patients; Lack of consistent messaging or sales

		force focus (e.g."BTCP" vs. "BTP"); Low awareness." "Rebranding Fentora from Illness to Wellness: Concept: Expand upon and continue to refine the FENTORA brand story to focus on successful treatment outcomes framed within patient functionality." Slide 11: Objective: Reinforce knowledge about BTP identification and evolve messaging from treatment matching to regaining/maintaining functional goals Slide 13: Objective: To increase HCP acceptance and awareness of BTP
2/17/2011	"Deaths From Prescription Pain Killers Still Rising," 2/17/2011, (Doc. 114).	Article discussing deaths from prescription painkillers and the opioid abuse epidemic. "The rise in abuse of and deaths from prescription opioid narcotics has reached epidemic proportions, government officials said today during a CDC event for physicians. There were more than 27,000 deaths from prescription drug overdoses in 2007, a number that has risen five-fold since 1990, according to data the agency presented during its latest "Grand Rounds" discussion, which features different public health topics. "Just about the only mortality statistic that is getting worse is death from prescription opioid abuse," said CDC director Thomas Frieden, MD, MPH, referring to a comprehensive report on the nation's health released yesterday that showed declining mortality rates for all other conditions, including heart disease and cancer."
12/8/2011	"Teva's Cephalon Wins Appeal Against Watson Over Fentora Copy", 12/8/2011, (Doc. 117).	Article regarding Fentora Sales only 160m, but Cephalon wins patent protection for Fentora until 2019. Teva Pharmaceutical Industries Ltd.'s Cephalon unit won an appeals court decision that prevents Watson Pharmaceuticals Inc. from selling a generic copy of the painkiller Fentora until 2019.

Endo was an active presence in the pain landscape well before the launch of Opana ER.

Endo had established ties with major pain organizations, both in conjunction with its products in

the opioid sphere, as well as other pain products, like Lidoderm. In 2001, Endo boasted that it had "leveraged our brand equity to gain recognition amongst the pain community". ENDO-OPIOID_MDL-02740220. Its Pain Management Expertise developed a "focused sales force and clinical education effort with: thorough knowledge of the pain management effort" and "well-established customer relationships with the pain management community and thought leaders." *Id.*

Endo developed a "pyramid of influence, where it spelled out the purpose of these relationships." *Id.* The pyramid illustrated the correlation between the amount of focus Endo would apportion to the various targeted groups and the resulting influence each category would yield. Endo would focus, in order of importance from least to greatest, on community prescribers, local advocates, regional opinion leaders and finally, national thought leaders. *Id.* In turn, the influence wielded by those at the top of the pyramid, the national thought leaders, would flow down to widening groups of regional opinion leaders and local advocates until it reached the largest group, community prescribers. *Id.* Endo recognized that developing relationships, peer influence and information could lead to a "competitive advantage for Endo" as well as 'expanded use of current and future products." ENDO-OPIOID_MDL-02344002.

Further, there had also concerns about the abuse liability of Percocet, one of Endo's most successful products. ENDO-CHI_LIT-00543481. To prepare the brand team for challenges to Opana, Endo hired crisis management company, Waggener Edstrom, and formed an Issues Management team to develop a crisis response plan for Opana ER. ENDO-CHI_LIT-00543507. Endo's concern was that "Misuse/Abuse risk perception may create negative environment and a PR crisis for OxyM and Endo pain franchise". ENDO-CHI_LIT-00543508. The goals of the crisis response included creating "supportive public policy environment for OxyM and C-II pipeline", fostering "responsible balance of legitimate patient access and risk management", and inoculating "against a PR crisis." *Id.* Internal documents compared this preparation to "Buying insurance", and

rationalized that "While there is no certainty that Endo will face the same kind of crisis in the commercialization of OxyM, we shouldn't assume that we won't." ENDO-CHI_LIT00543498. The Issues Management team recommended that Endo "'buy insurance' by investing time and energy now in preparing for a potential crisis so that potential harm may be minimized." *Id.*

Opana's 2007-2011 Business Plan included a strategy to "educate [health care providers] and payers on the role of opioids in pain management and their appropriate use and how Opana fits into this paradigm." By doing so, it would help Opana "gain entrée via perceived unmet need." ENDO-CHI_LIT 00545916.

The 2007-2011 business plan outlined strategies Opana could use to penetrate the market, including: 1) Differentiating Opana brand based on efficacy and dosing advantages; 2) Educating health care providers ("HCP") and payers on the role of opioids in pain management and their appropriate use and how Opana fits into this paradigm; 3) aggressively contracting with third party payers to gain and maintain required access; and 4) focusing Opana's resource deployment in order to penetrate market on as narrow a front as possible. *Id.* Each of these strategies would be executed by emphasizing the core messages of the brand. Opana ER's core messages were its "proven 12 hour dosing", its unique pharmacological profile that offered no known CYP450 drug-drug interaction effect, higher potency than oxycodone, low fluctuations between peak to trough plasma concentrations, long half-life, an lastly, its rapid relief due to max plasma concentration peaks within 30 minutes of oral administration. *Id.* Endo also positioned Opana ER as a good option for an opioid rotation regimen and touted the ease of using the FDA approved conversion chart from other opioids to Opana ER. *Id.* Lastly, Opana ER was promoted as one item in a continuum of care that included Opana IR for the relief of breakthrough and acute pain. *Id.* ENDO-CHI_LIT-00547253.

Endo identified a target audience of 950,000 medical care professionals, comprised of primary care physicians, specialists, nurses, nurse practitioners and physicians' assistants. ENDO-CHI_LIT-00547128. In its 2007 Single-Strategy Plan, Endo further drilled down into the target market, categorizing the various healthcare providers according to their willingness to consider prescribing opioids or whether they were already prescribing opioids. The most promising target segment was the "New Treatment Enthusiasts", comprised primarily of pain specialists. ENDO-CHI_LIT-00017403. This group alone accounted for 51% of the total prescriptions. *Id.*

As Opana ER progressed beyond the launch period, it continued to develop its core messages. In 2008, Endo unveiled a new message to alleviate doctor's concerns with prescribing opioids for patients with moderate to severe pain. In March 2008, a National Advisory Board of 23 experts convened by Endo to discuss the treatment of pain and the Opana brand suggested that Endo emphasize Opana ER's ability to simplify pain treatment. ENDO-CHI_LIT-00190053. The board recommended that the sales and marketing teams highlight the ability of Opana ER to simplify pain treatment and "do nothing to associate Opana ER with complexity of treatment of pain with opioids." *Id.* Sales representatives and product detail aids should focus on a "simple story for Opana." *Id.* Endo incorporated this information and other market research into an ad that asked, "Managing the complexities of Pain? Think Opana ER." ENDO-CHI_LIT-00023299. The 2008 Opana Brand Situation Analysis noted that "PCPs preferred hearing that the agent they selected for treatment would be less risky and therefore, easier for them; they reported a sense of calm after reading the 'simple' statement." *Id.* The 2009 Brand plan indicated that the brand would "continue to position Opana ER as the less complex choice for healthcare professionals in managing moderate to severe chronic pain patients." EPI001514810.

Endo's marketing materials suggested that treatment with Opana ER would improve patient's everyday life, not just relieve pain. The 2006-2010 Business Plan's positioning statement

framed Opana as "the preferred opioid that provided predictable, long-term relief across the widest spectrum of chronic pain conditions to make a real difference in everyday life." ENDO-CHI_LIT-00552969. The goal of the creative platform was to convince patients that "Life is better with Opana", relying on emotional, and unproven, benefits like comfort, predictability, functionality and shift of focus from a patient's pain to other aspects of their life. *Id.*

Endo integrated "quality of life" and "functionality" claims into a series of branded promotional materials released from 2007 through 2012. In one piece, "Bill the construction worker" is identified as a construction worker dependent on work to support his family. ENDO-CHI_LIT-00033952. His treatment was for moderate to severe lower back pain. *Id.* The materials note that his physician determined that Bill can appropriately use Opana ER for "continuous, around-the-clock opioid therapy." *Id.* Two patient profiles, released in 2011, "This is Frank" and "This is Ray", also featured similar patients who needed Opana in order to function in their everyday life. ENDO-CHI_LIT-00099937; ENDO-CHI_LIT-00120586. The patient featured in "This is Frank" had a complicated medical history and was taking several other medications. ENDO-CHI_LIT-00099937. Further, by highlighting the complicated medical history, Endo linked the material back to an Opana core message concerning lack of drug-drug interaction between Opana ER and other medications.*Id.* In a 2012 variation, Endo similarly combined its functional improvement claim with its core message of proven 12 hour relief. "Janice the Chef" suffered from chronic low back pain and needed relief that "lasts a full 12 hours." ENDO-CHI_LIT-00354604.

The brand positioning statement and the subsequent branded materials did not reveal the lack of data substantiating these claims. The 2008 Opana ER Brand Situational Analysis noted concerns that Opana ER "offered equal or less effective pain relief than competing drugs", "clinical practice has not substantiated efficacy claims made in marketing materials", and that it was "not effective for severe chronic pain." ENDO-CHI_LIT-00023299. Five years later, similar concerns

were raised in a 2012 Strategic Platform. Endo identified data gaps where additional data was needed to support Opana ER aspirational messages. It noted the need for a "proof-of-concept study analyzing productivity and ability of patients to work." ENDO-CHI_LIT-00467546. Endo further identified a need for "additional data showing the effects of Opana ER on cognitive impairment and judgment, combined with improvements in functionality and sleep, all lead to the best treatment experience for patients." *Id.*

In addition to branded materials, Endo regularly produced disease state awareness materials discussing chronic pain, pain management and treatment with opioids. The materials listed below demonstrate an effort to reach patients with messages on chronic pain treatment and opioid therapy. A sampling of materials demonstrates disease state awareness efforts beginning as early as 2004. Such materials include:

1. 2004-"Understanding Your Pain", patient directed material. ENDO-CHI_LIT-00237187.

    a. "Addicts take opioids for other reasons such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not an addiction." *Id.*

    b. "How can I be sure I'm not addicted? Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain maybe just to escape from your problems. Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons- to relieve your pain and improve your function. You are not addicted." *Id.*

    c. "Addiction IS NOT when a person develops 'withdrawal' (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped." *Id.*

    d. "Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal 'tolerance' to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out' of pain relief. Your dose can be adjusted or another medicine can be prescribed." *Id.*

e. "If you have taken opioid regularly for longer than a week, don't suddenly stop taking it. When your therapy is complete, your doctor will slowly decrease your dose safely." *Id.*

f. "If I take the Opioid Now, Will it Work Later When I Really Need It? – Some patients with chronic pain worry about this, but it is not a problem: The dose can be increased or other medicines can be added, you won't 'run out' of pain relief." *Id.*

2. 2008-"Taking a Long-Acting Opioid: What Does It Mean to Me", patient directed material. ENDO-CHI_LIT-00024520.

a. "Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*

b. "If you take an opioid regularly for longer than a week, don't suddenly stop, or decrease the dose by a large amount, because 'withdrawal' symptoms such as abdominal cramping or sweating can occur. When you no longer need this medicine, your healthcare provider will slowly decrease your dose safely." *Id.*

c. "Some people taking opioids may need to take a higher dose after a period of time in order to continue to have relief from their pain. This is a 'tolerance' to opioid medications that doesn't affect everyone who takes them, and does **NOT** mean addiction. If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*

3. 2009- Caregiver Booklet. ENDO-CHI_LIT-00541211.

a. "Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even it if may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*

b. "Most healthcare providers who treat people with pain agree that most people do not develop an addiction problem." *Id.*

c. "Withdrawal is not pleasant but does not harm the person. To avoid withdrawal problems, it is important to work with their healthcare provider to gradually reduce the dosage." *Id.*

d. "Chronic pain can be difficult to treat. It may require combinations of different medicines or the use of strong pain medicines called opioids. The goal of treating

chronic pain is to give the sufferer as much relief from pain as possible while letting them continue to function as much as possible." *Id.*

e. "If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*

4. 2009- Taking Long-Acting Opioids/Caregiver Guide. END00442270.

   a. "Most health care providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*

   b. "Most health care providers who treat patients with pain agree that most people do not develop an addiction problem." *Id.*

   c. "Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is not addiction." *Id.*

   d. "When someone takes an opioid for a while, they develop a physical dependence on it. If the medicine is stopped suddenly, the person may show signs of withdrawal, such as vomiting and shivering. Withdrawal is not pleasant but does not harm the person. To avoid withdrawal problems, it is important to work with their healthcare provider to gradually reduce the dosage." *Id.*

   e. "If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*

5. 2012- What you should know about treating your pain with opioids. ENDO-CHI_LIT-00277265.

   a. "Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your doctor." *Id.*

   b. "Just because you develop withdrawal symptoms if you miss a dose does not mean that you are addicted." *Id.*

   c. "The risk of becoming addicted to your opioid medicine is reduced if you take your medicine exactly as prescribed by your healthcare provider." *Id.*

6. 2012- Managing Pain with Opioids: Knowing the Facts. EPI002371945.

7. 2014- What you should know about treating Your Pain with Opioids. ENDO-CHI_LIT-00549936.

a. "Who may be at greater risk for addiction? - Addiction and abuse are more likely to happen if you smoke, already have a drug or alcohol problem, or if you have used illegal drugs in the past. If you have abused alcohol or drugs in the past, you may need to work with an addiction specialist while being treated with opioid medicine. Your healthcare provider can recommend an addiction specialist to help you manage the use of opioids to relieve your pain." *Id.*

b. "Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your health care provider. You should not change your dose on your own. Speak with your healthcare provider if you feel that you need to have your medicine adjusted." *Id.*

c. "Help is available if you need more relief - You may find over time that your medicine is not working as well to relieve your pain as when you first started taking it. This may be because your body has built up a tolerance to the medicine. . . . If you need more pain relief are having trouble sleeping, or are feeling depressed, tell your health care provider. Treatments may be available but a healthcare provider must always be the one to add medicine, change a prescription or adjust the dose. Medication may be one part of the solution." *Id.*

In anticipation of the initial approval date of 2003, Endo earmarked funds for a budget in support of the launch of Opana and Opana ER. The following year Endo received an approvable letter, indefinitely delaying the launch of Opana ER. ENDO-OPIOID_MDL-00279539. The funds were redirected that year with incremental funding resuming in 2004. The total advertising and promotional budget jumped significantly in 2006, the year that Opana ER received FDA approval. ENDO-CHI_LIT-00552982. Below is a chart outlining the advertising and promotional expenditures from 2002 through 2017.

A&P Marketing budget for Opana Franchise		
YEAR	**TOTAL**	**BATES BEG**
2002	$2,000,000	END00001522*[6]
2003		
2004	$2,280,000	ENDO-OPIOID_MDL-02149982
2005	$1,691,000	ENDO-OPIOID_MDL-02149982
2006	$18,027,000	END00000923
2007	$19,758,404	EPI000560276

[6] Annual budget includes Market Research Spending.

2008	$25,279,282	EPI000560276
2009	$17,756,000	EPI001474537
2010	$15,332,000	EPI001474537
2011	$15,130,000	ENDO-CHI_LIT-00439415
2012	$19,540,000	ENDO-CHI_LIT-00439415
2013	$21,650,000	ENDO-CHI_LIT-00439415
2014	$1,603,870	ENDO-CHI_LIT-00549855
2015	$750,000	ENDO-CHI_LIT-00549855
2016	$1,500,000	ENDO-CHI_LIT-00551619
2017		

Training materials utilized by the sales representatives taught specific topics, like low back pain in patients. EPI001554204. These modules gave a comprehensive overview of potential conditions that might necessitate treatment with Opioids, yet they downplayed the risks that opioid medication itself posed. In the low back pain training module, sales representatives learned that "there is a potential for addiction, although this may be less than commonly believed when these medications are used for pain relief." EPI001554204. It further noted that "[w]hen prescribed properly the use of opioids for chronic pain can be, in some cases, safer than ongoing use of NSAIDS." *Id.*

Sales reps were also coached on concepts like pseudo addiction. A 2006 training manual on the Oxymorphone Risk Management Plan defined pseudo addiction as "an iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted." ENDO-CHI_LIT-00053284. The manual noted that "physicians can differentiate addiction from pseudo addiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief." *Id.* It offered further reassurance that "[pseudoaddictive behaviors such as clock watching (counting down the time until the next dose) will resolve when the pain is properly treated. *[AAPM,2001, 3]." Id.*

The manual also downplayed and mischaracterized the risk of physical dependence, comparing physical dependence on opioids to "chronic use of many types of drugs, including many that are not associated with addiction or abuse (such as beta blockers for high blood pressure)." *Id.* Physical dependence was further positioned as an alternative to addiction and explained in the following manner:

> [p]hysical dependence can be mistaken for addiction, because in some cases a patient may insist on continued use of the opioid even when pain has resolved, to avoid withdrawal symptoms experience when they try to stop. *[AAPM, 2001, 3]*. Withdrawal symptoms can be avoided or managed by carefully-tapering off the dose once pain relief is achieved. *Id.*

Tolerance to a drug was also offered as an alternative explanation for drug-seeking behavior. Defined as "the body trying to overcome the effects of the drug", the manual cautioned "[t]olerance can be mistaken for addiction because the patient may ask for increasing doses of the opioid, which can be perceived as 'drug-seeking behavior'." *Id.* The section concluded:

> the presence of physical dependence and/or tolerance is not sufficient to state that a person is addicted. Patients treated with prolonged opioid therapy do not usually develop addictive disorders, though the actual risk is unknown and likely varies with genetic disposition, among other factors. [*AAPM,2001, 2*] *Id.*

The manual reassured that addiction was different from tolerance and dependence as,

> [a]ddiction is a disorder and not an expected consequence of taking an opioid. By contrast, tolerance and physical dependence are expected physical phenomena associated with opioid use. [*AAPM, 2001, 3*] Tolerance and physical dependence can be mistaken for addiction so the physician must pay close attention to distinguish them from each other. *Id.*

Below is a table summarizing frequent issues covered by the District Managers in the Coaching Reports to their sales team members.

Message	Date	Region	Bates
Frequency of Calls			

Message	Date	Region	Bates
You've made 30 calls on your Fab 5 from Nov 1 to Nov 25, that's about 5 calls apiece. Keep that focus on those 5 docs.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
Hyper Target 5 Top Key physicians 2= times per week (the Fab 5)	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353
I would like to see you push your prescribers a bit more for real answers. Dr. Van Ginkel has been promising you to write for over a year. He is decile 9 and has not really written Opana considering you have been in his office 25 times this year and have over 80 total calls logged in with him,	4/3/2008	South Miami, FL	ENDO-CHI_LIT-00078382
Insure you are achieving a high frequency of calls against your top 10 OPANA ER targets- minimum 1 calls a week and 2 calls a week against your top 5 prescribers.	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
Detailing – use of funds			
You have spent your DME on your fab 5 with good focus (Dr. Black, coffee each Monday; lunches with the others) keep that up.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
You got two of your top Opana ER docs and one good potential Opana ER doc on an Opana ER conference call by bringing dinner to their offices… that's outstanding!	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
With Dr. Baresh, our lunch centered around managed care (which was VERY helpful to understanding the recent changes) and did spend time with a clinical discussion around the benefits of Opana ER for	2/17/2007	Dayton, OH	ENDO-CHI_LIT-00045831

Message	Date	Region	Bates
opioid therapy.			
Always demonstrates effective use of DME funds to promote access, build rapport and extend dialogue... You are the top spender…but also the most effective	8/21/2008	Chillicothe, OH	ENDO-OPIOID_MDL-00786258
Efficacy			
The message was good today. I heard "Durable Efficacy" and Dosing advantages" on all Opana calls. Make sure to take the time to give a clear explanation of what they mean as you did with Dr. Barnard.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355.
Make sure to take the time and get conversation going on Durable Efficacy and Dosing Advantages. Like we talked about w/ Dr. Roach, focus the BENEFITS of those features on what's important to them (his case was ways that DE and DA could help him deal with his fears of addiction (predictable dosing and limited dose increases).	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353
Talk about dosing in general and the importance and pitalls. With durable efficacy talk about tolderance, dose increasing with chronic pain and some of the problems with the overuse of rescue meds.	5/25/2007	North Albuquerque, NM	ENDO-OPIOID_MDL-00684008
You did a good job of presenting Opana ER while addressing questions about abuse, conversion and efficacy from the NPs. I agree that a roundtable would be extremely beneficial in this office.	10/24/2007	Hattiesburg, MS	ENDO-OPIOID_MDL-00688336

Message	Date	Region	Bates
"Stay ahead of the pain", being "released from the grip of pain" are taglines that stand out and should be used along with the MVA. These types of statements combined with a thorough and compelling message should help your docs remember Opana better.	10/2/2006	Huntsville, AL	ENDO-OPIOID_MDL-00678060
DM suggestions for messaging "I want to insure(sic) I am properly properly presenting OPANA ER to insure(sic) that your patients have the chance to try this new medication- I believe in my hear(sic) that some of these patients will have profound and life changing improvement"	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
DM suggestions for messaging "Doctor wouldn't you agree that OPANA ER's true Q12 dosing and limited need recue meds will lead to better pain control and allow you(sic) patients to confidently return to a more active life?"	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *03.
Minimization of Risk			
Responds to objections and questions by repositioning product and highlighting benefits.	2/17/2001	Dayton, OH	ENDO-CHI_LIT-00045831
Building upon out previous ride along we need to help the physician in identifying the unique needs they and their patients have in chronic pain management and how OPANA ER provides an effective and potentially safer solution,	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
Reinforce patients studied >2,500 side effect profile	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289

Message	Date	Region	Bates
similar to other opioids ad well tolerated once properly titrated, the only strong opioid that does not interfere with the CYP 450 system (piece of mind for you and the patient), does not dose dump, low level of undesired side effects <1% of patients report euphoric mood in clinical trials. Safe to use on both opioid experienced and opioid naïve patients.			
Sales rep directed to "Read the Avoiding Opioid Abuse book…practice and time is what is needed at this time along with a greater understanding of the Opioid market and the disease state along with more- in depth comfort and knowledge associated with Opana ER.	10/20/2008	West Toledo, OH	ENDO-OPIOID_MDL-00700292
Comparison to other Opioids			
How are you different from Oxycontin was the one that we heard most. Good answers to that. CYP 450, true Q 12, extensively studied, etc.	8/22/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00677219
You asked some good questions to uncover needs. "How many rescue meds do your patients take, how many is too many? Do they take too many oxy ER?	5/23/2007	North Albuquerque, NM	ENDO-OPIOID_MDL-00684008
We reviewed your top Oxycontin writers, You should live with these people weekly to get them to write Opana. This is the low hanging fruit that is paying dividends for your counterparts.	10/2/2006	Huntsville, AL	ENDO-OPIOID_MDL-00678060

Message	Date	Region	Bates
You were able to get the physicin to share with you a patient he has that would benefit from OPANA ER therapy! The patient was on Oxycontin and was using a large quantity of PRN medications and you effectively used your MVA to and the opioid experienced patient data to deliver a key benefit of OPANA ER therapy- fewer occasions for PRN meds because of its true Q12 dosing and durability of effect.	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *03
Local speaker program promotion			
You have 3 of your Fab 5 scheduled to go to the Opana ER Speakers program… THAT's OUTSTANDING!!! I guarantee that this will help your business grow!	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353.
CEDRIC push the upcoming dinner program in you have in Jacksonville with Dr. Argoff on March 19th. This is a great opportunity to get your Fab 5 doctors in front of a national thought leader and stimulate utilization of OPANA ER.	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *04

Manufacturer	Deponent	Deposition Cite
Allergan	Julie Snyder	271:5-24; 272:1-3
Endo	Ronald Perry Wickline	196:3-8; 197:6-25
Janssen	Kimberly Deem-Eshleman	55:9-15; 129:1-15
Purdue	Phil Cramer (30)(b)(6)	Cramer 170:10-25; 171-1-10
Teva	John Hassler (30)(b)(6)	275:14-24;276:1-5

Cephalon (aquired by Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5
Activas (subsidy of Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5
Watson (supsidy of Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5

On February 15, 2013, Endo submitted a labeling supplement proposing additions to the label including "pre-and postmarketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section of the Package Insert." ENDO-OR-CID-01174358. On May 10, 2013, the FDA denied the application and highlighted the following concerns about the formulation:

> no pharmacokinetic studies measuring serum concentrations following nasal administration or assessing the ability to insufflate have been conducted. Additionally, no human abuse liability studies examining abuse by the nasal route of administration have been conducted. The ease with which the product can be manipulated, and the ease with which oxymorphone can be extracted from the manipulated product, are not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of Opana ER. *Id.* at *58-59.

The FDA also cited concerns with the post marketing data Endo submitted in support of the label change. The FDA found,

> [t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:
>
> - the short period of time represented
> - the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
> - the continued availability of original OPANA ER throughout the reporting period
> - the possible misclassification of the original and reformulated products based on the similar appearance of the two products.

ENDO-OR-CID-01174359.

Mallinckrodt

Overall launch/brand/marketing plans

a) MNK-T1-0000126200, MNK Power Point presentation re: marketing MNK-795 (extended release formulation of oxycodone and acetaminophen)
b) MNK-T1_0000110204, Mallinckrodt Power Point presentation "Situation Analysis" on opioid prescription market and potential market for Xartemis XR and MNK 155
c) MNK-T1-0000124210, MNK PowerPoint presentation re business results, marketing strategy, and market overview for EXALGO
d) MNK-T1_0000535244, e-mail chain re marketing to physicians
e) MNK-T1-0000130448, E-mail re marketing message for XARTEMIS XR
f) MNK-T1-0000132919, Internal instructions to sales teams re XARTEMIS sales; See also. MNK-T1_0000132938.
g) MNK-T1-0000228064, PowerPoint presentation re marketing strategy for promoting MNK-795
h) MNK-T1-0000136453, Leave-fyrBehind for marketing XARTEMIS
i) MNK-T1_0000110977, e-mail re distribution of Medsaway
j) MNK-T1_0000102151
k) MNK-T1_0000132471, e-mail ad copy for Xartemis
l) MNK-T1_0000132411, digital leave behind
m) MNK-T1_0000546808, sales rep compensation plan
n) MNK-T1_0000468961, discusses global strategic marketing plan
o) MNK-T1_0000222031, Advocacy and Pain Franchise presentation

Disease awareness/chronic pain as a condition

a) MNK-T1_0000117179

Detailing – who's targeted, frequency of visits, key issues from scripts and call notes

a) MNK-T1_0000113374, power-point for sales reps
b) MNK-T1_0000542035, e-mail re pharmacy and doctor profiling
c) MNK-T1_0000541200, sales newsletter discussing meeting with doctors
d) MNK-T1_0000136719, PowerPoint re market research on Xartemis XR
e) MNK-T1_0000207584, proposed manuscript re targeting physicians
f) MNK-T1_0000093660 through 93682
g) MNK-T1_0000542039, Instructions and screenshots of pharmacy profiling system.
h) MNK-T1_0000546493, Presentation about "high value physicians"
i) MNK-T1_0000541200, sales newsletter
j) MNK-T1_0000130216, e-mail re Xartemis Sales
k) MNK-T1_0000545754, e-mail re Xartemis Sales
l) MNK-T1_0000545281, e-mail re sales rep results

m) MNK-T1_0000255243, presentation re targeting opioid prescribers

Copayment Cards/Vouchers/Rebates

a) MNK-T1_0000541720
b) MNK-T1_0000286297, chargeback reports for sales of Oxy 15 and 30
c) MNK-T1_0000540013, PowerPoint re marketing expenses and relates for FY13
d) MNK-T1_0000193448
e) MNK-T1_0000215747, promotional material that explains PPI program
f) MNK-T1_0000227707, Contract with AmerisourceBergen for rebates in 2010
g) MNK-T1_0000506620, Rebate information for 2006-2007 for Keysource medical
h) MNK-T1_0000508354, E-mail re Vault incentive program
i) MNK-T1_0000508355, Data for sales relating to Vault incentive program
j) MNK_T1_0000483901, Data on chargebacks and rebate programs for October FY11

Specific Misrepresentations

a) MNK-T1_0000180846, email discussing marketing strategy for MNK 795, "the profile is less-liked by recreational drug abusers due to the controlled release, which makes it a potentially less abusable alternative to Percocet and Oxycontin"
b) MNK-T1_0000111315 Email update from Melissa Falcone to the Brand Sales Team "SCORE," discussing the messaging around Xartemis XR and Exalgo
c) MNK-T1_0000116055 E-mail discussing Pharmacy messaging
d) MNK-T1_0000113702, presentation summaries for Xartemis XR ad campaign
e) MNK-T1_0000125729, EXALGO Presentation
f) MNK-T1_0000102151, guide for media inquiries
g) MNK-T1_0000132471, e-mail ad copy for Xartemis
h) "[T]he majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others. "Date: 2013. Source: Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse at 3, https://www2.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147485834

Promotion of the book Defeat Chronic Pain Now!

a) "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction. "Date: 2012. Book is still available online. Source: Mallinckrodt promoted a book through C.A.R.E.S. Alliance: Defeat Chronic Pain Now! p. 177 http://www.defeatchronicpainnow.com/

b) "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain. "Defeat Chronic Pain Now! at p. 178.

c) "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy." Date: 2012. Book is still available online. Source: Mallinckrodt promoted a book through C.A.R.E.S. Alliance: Defeat Chronic Pain Now! at p. 174

d) "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving. "Date: 2012. Book is still available online at p. 176.

e) "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction." FDate: 2012. Book is still available online. at p. 179.

Medsaway Initiative for Patient Safety Awareness

a) MNK-T1_0000546362
b) MNK-T1_0000546404

Government Affairs

a) MNK-T1_0000214460, Government Affairs Presentation
b) MNK-T1_0000239120, Advocacy and Government Affairs Tactical Plan by Kevin Webb

Coordination with other Defendants

a) MNK-T1_0000227707, Presentation on collaboration between Endo and MNK to promote MNK-795
b) ALLERGAN_MDL_01239440, Document showing coordination among manufacturers for REMS (Risk Evaluation and Mitigation Strategy)
c) ALLERGAN_MDL_01237617, Joint Meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee on drug safety and REMS for Extended-Release and Long-Acting Opioid Products
d) ALLERGAN_MDL_01188848, speaker presentation for risk mitigating efforts
e) ALLERGAN_MDL_01358391, presentation re joint meeting and weekly All Hands All, Opioid REMS Program Management
f) ENDO-CHI-LIT_00238974, joint meeting presentation re risk management advisory committees

Dated: March 18, 2019

Respectfully submitted,
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CERTIFICATE OF SERVICE

I, Joseph L. Ciaccio, certify that on this 18th day of March 2019, I caused the foregoing to be served via electronic mail on Defendant's Liaison Counsel pursuant to the Case Management Order. *See* Dkt. No. 232.

s/ Joseph L. Ciaccio